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Country of approval	Product name	Manufacturer/applicant name	Link
United States	TRUPCR SARS-CoV-2 Kit	3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit	BioTNS Co. Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Pro-AmpRT SARS-CoV-2 Test	Pro-Lab Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Infinity BiologiX TaqPath SARS-CoV-2 Assay	Infinity BiologiX LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	GetMyDNA COVID-19 Test Home Collection Kit	GetMyDNA	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Lyra Direct SARS-CoV-2 Assay	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	TaqPath COVID-19 Pooling Kit	Thermo Fisher Scientific Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Aptima SARS-CoV-2 assay	Hologic, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Bio-Speedy Direct RT-qPCR SARS-CoV-2	Bioeksen R&D Technologies Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Smart Detect SARS-CoV-2 rRT-PCR Kit	InBios International, Inc	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quaeris SARS-CoV-2 Assay	Harvard University Clinical Laboratory (HUCL)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	Wadsworth Center, New York State Department of Public Health	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Genetron SARS-CoV-2 RNA Test	Genetron Health (Beijing) Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LetsGetChecked Coronavirus (COVID-19) Test	LetsGetChecked, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Kroger Health COVID-19 Test Home Collection Kit	The Kroger Co.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	EmpowerDX COVID-19 Home Collection Kit DTC	Clinical Enterprise, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Viracor SARS-CoV-2 assay DTC	Viracor Eurofins Clinical Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test	LGC, Biosearch Technologies	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Phosphorus COVID-19 RT-qPCR Test	Phosphorus Diagnostics LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC	Phosphorus Diagnostics LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Phosphorous COVID19 RT-qPCR Test DTC	Phosphorus Diagnostics LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	cobas SARS-CoV-2	Roche Molecular Systems, Inc. (RMS)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	GENETWORx Covid-19 Nasal Swab Test	RCA Laboratory Services LLC dba GENETWORx	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	binx health At-Home Nasal Swab COVID-19 Sample Collection Kit	binx health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3)	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 RT-PCR Test	Laboratory Corporation of America (Labcorp)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Linea COVID-19 Assay Kit	Applied DNA Sciences, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Pixel by LabCorp COVID-19 Test Home Collection Kit	Laboratory Corporation of America (LabCorp)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 Coronavirus Real Time PCR Kit	Jiangsu Biopertectus Technologies Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits	Gravity Diagnostics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BioFire COVID-19 Test	BioFire Defense, LLC	For updated information on all products listed by the FDA use this link:

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			https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Clarifi COVID-19 Test Kit	Quadrant Biosciences Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Aptima SARS-CoV-2/Flu assay	Hologic, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit	Bio-Rad Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SalivaDirect At-Home Collection Kit	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MassARRAY SARS-CoV-2 Panel	Agena Bioscience, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Ezplex SARS-CoV-2 G Kit	SML GENETREE Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BD SARS-CoV-2 Reagents for BD MAX System	Becton, Dickinson and Company (BD)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	AQ-TOP COVID-19 Rapid Detection Kit PLUS	SEASUN BIOMATERIALS, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Ambry COVID-19 RT-PCR Test	Ambry Genetics Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BD SARS-CoV-2/Flu for BD MAX System	Becton, Dickinson and Company (BD)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	DxTerity SARS-CoV-2 RT PCR CE Test	DxTerity Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Genetrack SARS-CoV-2 Molecular Assay	Genetrack Biolabs, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)	BioFire Diagnostics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay	NeuMoDx Molecular, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	EURORealTime SARS-Cov-2	Euroimmun US, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Illumina COVIDSeq Test	Illumina, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Lyra SARS-CoV-2 Assay	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	OPTI SARS-CoV-2 RT PCR Test	OPTI Medical Systems, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Xpert Omni SARS-CoV-2	Cepheid	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Kaiser Permanente High Throughput SARS-CoV-2 Assay	Southern California Permanente Medical Group	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	DetectX-Rv	PathogenDx, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2	STS Lab Holdco (a subsidiary of Amazon.com Services LLC)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Color COVID-19 Self-Swab Collection Kit with Saline	Color Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	SynergyDx SARS-CoV-2 RNA Test DTC	Synergy Diagnostic Laboratory, Inc., DBA SynergyDx	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SynergyDx SARS-CoV-2 RNA Test	Synergy Diagnostic Laboratory, Inc., DBA SynergyDx	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Allplex 2019-nCoV Assay	Seegene, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Color SARS-CoV-2 RT-LAMP Diagnostic Assay	Color Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Clinical Enterprise SARS-CoV-2 RT-PCR Assay	Clinical Enterprise, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC	Clinical Enterprise, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Fulgent COVID-19 by RT-PCR Test	Fulgent Therapeutics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit	PerkinElmer Genomics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	SalivaDirect	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Lucira CHECK-IT COVID-19 Test Kit	Lucira Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit	Thermo Fisher Scientific	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	FTD SARS-CoV-2	Fast Track Diagnostics Luxembourg S.à.r.l. (a Siemens Healthineers Company)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PhoenixDx SARS-CoV-2 Multiplex	Trax Management Services Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	covidSHIELD	University of Illinois Office of the Vice President for Economic Development and Innovation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Simplexa COVID-19 Direct assay	DiaSorin Molecular LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	PerkinElmer, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	P23 Labs TaqPath SARS-CoV-2 Assay	P23 Labs, LLC.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	cobas SARS-CoV-2 & Influenza A/B	Roche Molecular Systems, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Verily COVID-19 RT-PCR Test	Verily Life Sciences	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Gravity Diagnostics SARS-CoV-2 RT-PCR Assay	Gravity Diagnostics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	KPMAS COVID-19 Test	Kaiser Permanente Mid-Atlantic States	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2	BGI Genomics Co. Ltd	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LumiraDx SARS-CoV-2 RNA STAR Complete	LumiraDx UK Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Cue COVID-19 Test	Cue Health Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Solana SARS-CoV-2 Assay	Quidel Corporation	For updated information on all products listed by the FDA use this link:

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United States	iC SARS-CoV2 Test	Tempus Labs, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 NGS Assay	Twist Bioscience Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Color COVID-19 Self-Swab Collection Kit	Color Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Color COVID-19 Self-Swab Collection Kit DTC	Color Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC	Color Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Cue COVID-19 Test for Home and Over The Counter (OTC) Use	Cue Health Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Alinity m Resp-4-Plex	Abbott Molecular Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	NxTAG Respiratory Pathogen Panel + SARS-CoV-2	Luminex Molecular Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Advanta Dx SARS-CoV-2 RT-PCR Assay	Fluidigm Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	TaqPath COVID-19 Combo Kit	Thermo Fisher Scientific, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	AQ-TOP COVID-19 Rapid Detection Kit	Seasun Biomaterials, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Assurance SARS-CoV-2 Panel DTC	Assurance Scientific Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Everlywell COVID-19 Test Home Collection Kit DTC	Everlywell, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	Bio-Rad Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	TaqPath COVID-19, FluA, FluB Combo Kit	Thermo Fisher Scientific	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Procleix SARS-CoV-2 Assay	Grifols Diagnostic Solutions Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	U-TOP COVID-19 Detection Kit	SEASUN BIOMATERIALS	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	QDX SARS-CoV-2 Assay	QDx Pathology Services	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Visby Medical COVID-19 Point of Care Test	Visby Medical, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CareStart COVID-19 MDx RT-PCR	Access Bio, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Clinomics TrioDx RT-PCR COVID-19 Test	Clinomics USA Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Accula SARS-Cov-2 Test	Mesa Biotech Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QuantiVirus SARS-CoV-2 Test kit	DiaCarta, Inc	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	IntelliPlex SARS-CoV-2 Detection Kit	PlexBio Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	DSL COVID-19 Assay	Diagnostic Solutions Laboratory, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay	Sandia National Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Alpha Genomix TaqPath SARS-CoV-2 Combo Assay	Alpha Genomix Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BayCare SARS-CoV-2 RT PCR Assay	BayCare Laboratories, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Xpert Xpress SARS-CoV-2/Flu/RSV	Cepheid	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	NeoPlex COVID-19 Detection Kit	GeneMatrix, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Panther Fusion SARS-CoV-2 Assay	Hologic, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	NeuMoDx SARS-CoV-2 Assay	NeuMoDx Molecular, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Express Gene 2019-nCoV RT-PCR Diagnostic Panel	Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Cleveland Clinic SARS-CoV-2 Assay	Cleveland Clinic Robert J. Tomsich Pathology	For updated information on all products listed by the FDA use this link:

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		and Laboratory Medicine Institute	https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BD MAX COVID-19 ASSAY (Authorized by HHS/OASH)	Hospital of the University of Pennsylvania	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PMSF-INNO SARS-CoV-2 RT-PCR Test (Authorized by HHS/OASH)	INNO Diagnostics Reference Laboratory, Ponce Medical School	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 real time RT-PCR test (Authorized by HHS/OASH)	University of Louisville Infectious Diseases Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Sherlock CRISPR SARS-CoV-2 Kit	Sherlock BioSciences, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay	Centers for Disease Control and Prevention (CDC)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Xpert Xpress SARS-CoV-2 test	Cepheid	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ExProbe SARS-CoV-2 Testing Kit	TBG Biotechnology Corp.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Primerdesign Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Quick SARS-CoV-2rRT-PCR Kit	Zymo Research Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	AMPIPROBE SARS-CoV-2 Test System	Enzo Life Sciences, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Biomeme SARS-CoV-2 Real-Time RT-PCR Test	Biomeme, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	iAMP COVID-19 Detection Kit	Atila BioSystems, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 Fluorescent PCR Kit	Maccura Biotechnology (USA) LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Fosun COVID-19 RT-PCR Detection Kit	Fosun Pharma USA Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	SolGent Co., Ltd	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Omni COVID-19 Assay by RT-PCR	Omnipathology Solutions Medical Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	GenePro SARS-CoV-2 Test	Gencurix, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Laboratorio Clinico Toledo SARS-CoV-2 Assay	Laboratorio Clinico Toledo	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Gene By Gene SARS-CoV-2 Detection Test	Gene By Gene	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Real-Q 2019-nCoV Detection Kit	BioSewoom, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QuantiVirus SARS-CoV-2 Multiplex Test Kit	DiaCarta, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Solaris Multiplex SARS-CoV-2 Assay	Solaris Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LumiraDx SARS-CoV-2 RNA STAR	LumiraDx UK Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Guardant-19	Guardant Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay	Texas Department of State Health Services, Laboratory Services Section	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	T2SARS-CoV-2 Panel	T2 Biosystems, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Kaira 2019-nCoV Detection Kit	OPTOLANE Technologies, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Visby Medical COVID-19	Visby Medical, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Clear Dx SARS-CoV-2 Test	Clear Labs, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	UMass Molecular Virology Laboratory 2019-nCoV rRT-PCR Dx Panel	UMass Memorial Medical Center	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Alinity m SARS-CoV-2 assay	Abbott Molecular Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Xpert Xpress SARS-CoV-2 DoD	Cepheid	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	BioCore 2019-nCoV Real Time PCR Kit	BioCore Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MatMaCorp COVID-19 2SF Test	Materials and Machines Corporation of America (DBA MatmaCorp, Inc.)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PacificDx Covid-19	ResearchDx, Inc., DBA Pacific Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System	Roche Molecular Systems, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Bio-Rad SARS-CoV-2 ddPCR Test	Bio-Rad Laboratories, Inc	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	DxTerity SARS-CoV-2 RT-PCR Test	DxTerity Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BioCode SARS-CoV-2 Assay	Applied BioCode, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Quest Diagnostics RC COVID-19+Flu RT-PCR	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Rheonix COVID-19 MDx Assay	Rheonix, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC)	Centers for Disease Control and Prevention's (CDC)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quest Diagnostics RC SARS-CoV-2 Assay	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 RT-PCR Assay	Stanford Health Care Clinical Virology Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	RapidRona Self-Collection Kit	RapidRona, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Lucira COVID-19 All-In-One Test Kit	Lucira Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quest SARS-CoV-2 rRT-PCR	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	SARS-CoV-2 Test Kit (Real-time PCR)	Xiamen Zeesan Biotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-COV-2 R-GENE	BioMérieux SA	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Wantai SARS-CoV-2 RT-PCR Kit	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	NxTAG CoV Extended Panel Assay	Luminex Molecular Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ARIES SARS-CoV-2 Assay	Luminex Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ORAcollect-RNA OR-100 and ORAcollect-RNA ORE-100 saliva collection devices	DNA Genotek Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	OMNIgene-ORAL OM-505 and OME-505 (OMNIgene-ORAL) saliva collection devices	DNA Genotek Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Helix COVID-19 Test	Helix OpCo LLC	For updated information on all products listed by the FDA use this link:

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			https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Wren Laboratories COVID-19 PCR Test	Wren Laboratories LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SDNA-1000 Saliva Collection Device	Spectrum Solutions LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	UCLA SwabSeq COVID-19 Diagnostic Platform	University of California, Los Angeles (UCLA)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ePlex Respiratory Pathogen Panel 2	GenMark Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit	Detectachem Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Cuur Diagnostics SARS-CoV-2 Molecular Assay	Cuur Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Aeon Global Health SARS-CoV-2 Assay	Aeon Global Health	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	CentoSure SARS-CoV-2 RT-PCR Assay	CENTOGENE US, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Akron Children's Hospital SARS-CoV-2 Assay	Akron Children's Hospital	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 MassArray Test	National Jewish Health	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	AvellinoCoV2 test	Avellino Lab USA, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	OraRisk COVID-19 RT-PCR	Access Genetics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Acupath COVID-19 Real-Time (RT-PCR) Assay	Acupath Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BioGX SARS-CoV-2 Reagents for BD MAX System	Becton, Dickinson & Company (BD)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	ScienCell Research Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	LabGun COVID-19 RT-PCR Kit	LabGenomics Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ViroKey SARS-CoV-2 RT-PCR Test v2.0	Vela Operations Singapore Pte. Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QIAstat-Dx Respiratory SARS-CoV-2 Panel	QIAGEN GmbH	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Assurance SARS-CoV-2 Panel	Assurance Scientific Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Gravity Diagnostics COVID-19 Assay	Gravity Diagnostics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	HDPCR SARS-CoV-2 Assay	ChromaCode Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	HealthQuest Esoterics TaqPath SARS-CoV-2 Assay	HealthQuest Esoterics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Psoma COVID-19 RT Test	Psomagen, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	PowerChek 2019-nCoV Real-time PCR Kit	KogeneBiotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Boston Heart COVID-19 RT-PCR Test	Boston Heart Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Lilly SARS-CoV-2 Assay	Eli Lilly and Company	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Ethos Laboratories SARS-CoV-2 MALDI-TOF Assay	Ethos Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 (N gene detection) Test	Exact Sciences Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PCL SARS-CoV-2 Real-Time RT-PCR Assay	Patients Choice Laboratories, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	KimForest SARS-CoV-2 Detection Kit v1	KimForest Enterprise Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	GK ACCU-RIGHT SARS-CoV-2 RT-PCR KIT	GK Pharmaceuticals Contract Manufacturing Operations	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	ID NOW COVID-19	Abbott Diagnostics Scarborough, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Everlywell COVID-19 Test Home Collection Kit	Everlywell, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	qSanger-COVID-19 Assay	BillionToOne, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MiraDx SARS-CoV-2 RT-PCR assay	MiraDx	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 DETECTR Reagent Kit	Mammoth Biosciences, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quest Diagnostics PF SARS-CoV-2 Assay	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Quest Diagnostics HA SARS-CoV-2 Assay	Quest Diagnostics Infectious Disease, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ePlex SARS-CoV-2 Test	GenMark Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	COVID-19 Nucleic Acid RT-PCR Test Kit	ZhuHai Sinochips Bioscience Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Hymon SARS-CoV-2 Test Kit	dba SpectronRX	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	PhoenixDx 2019-CoV	Trax Management Services Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	GWU SARS-CoV-2 RT-PCR Test	George Washington University Public Health Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Helix COVID-19 NGS Test	Helix OpCo LLC (dba Helix)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ViroKey SARS-CoV-2 RT-PCR Test	Vela Operations Singapore Pte Ltd	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Poplar SARS-CoV-2 TMA Pooling assay	Poplar Healthcare	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Genus SARS-CoV-2 Assay	ISPM Labs, LLC dba Capstone Healthcare	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	UCSD RC SARS-CoV-2 Assay	University of California San Diego Health	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Abbott RealTime SARS-CoV-2 assay	Abbott Molecular	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CRL Rapid Response	Clinical Reference Laboratory, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Novel Coronavirus (SARS-CoV-2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing)	Jiangsu CoWin Biotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Compass Laboratory Services SARS-CoV2 Assay	Compass Laboratory Services, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BMC-CReM COVID-19 Test	Boston Medical Center	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 RNA DETECTR Assay	UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CentoFast-SARS-CoV-2 RT-PCR Assay	CENTOGENE US, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel	LifeHope Labs	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Inform Diagnostics SARS-CoV-2 RT-PCR Assay	Inform Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR)	PreciGenome LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay	University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	FRL SARS CoV-2 Test	University of Alabama at Birmingham Fungal Reference Lab	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	OSUWMC COVID-19 RT-PCR test	The Ohio State University Wexner Medical Center	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Diagnovital SARS-CoV-2 Real-Time PCR Kit	RTA Laboratories Biological Products Pharmaceutical and Machinery Industry	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Curative-Korva SARS-Cov-2 Assay	KorvaLabs Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	DTPM COVID-19 RT-PCR Test	Tide Laboratories, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	1copy COVID-19 qPCR Multi Kit	1drop Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Gnomegen COVID-19-RT-qPCR Detection Kit	Gnomegen LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Sansure BioTech Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Gnomegen COVID-19 RT-Digital PCR Detection Kit	Gnomegen LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	STANDARD M nCoV Real-Time Detection Kit	SD Biosensor, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	RealStar SARS-CoV02 RT-PCR Kits U.S.	altona Diagnostics GmbH	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	GeneFinder COVID-19 Plus RealAmp Kit	OSANG Healthcare	For updated information on all products listed by the FDA use this link:

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			https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	GS"ç COVID-19 RT-PCR KIT	GenoSensor, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit	Co-Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Alimetrix SARS-CoV-2 RT-PCR Assay	Alimetrix, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COV-19 IDx assay	Ipsium Diagnostics, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Sienna-Clarity COVID-19 Antigen Rapid Test Cassette	Salofa Oy	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Celltrion DiaTrust COVID-19 Ag Rapid Test	Celltrion USA, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SCoV-2 Ag Detect Rapid Test	InBios International, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BinaxNOW COVID-19 Ag Card	Abbott Diagnostics Scarborough, Inc.	For updated information on all products listed by the FDA use this link:

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			https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LumiraDx SARS-CoV-2 Ag Test	LumiraDx UK Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CareStart COVID-19 Antigen test	Access Bio, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BD Veritor System for Rapid Detection of SARS-CoV-2	Becton, Dickinson and Company (BD)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Omnia SARS-CoV-2 Antigen Test	Qorvo Biotechnologies, LLC.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BinaxNOW COVID-19 Ag Card Home Test	Abbott Diagnostics Scarborough, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Sofia SARS Antigen FIA	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BinaxNOW COVID-19 Antigen Self Test	Abbott Diagnostics Scarborough, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QuickVue At-Home OTC COVID-19 Test	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	BinaxNOW COVID-19 Ag Card 2 Home Test	Abbott Diagnostics Scarborough, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BinaxNOW COVID-19 Ag 2 Card	Abbott Diagnostics Scarborough, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LIAISON SARS-CoV-2 Ag	DiaSorin, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B	Becton, Dickinson and Company (BD)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	Ortho Clinical Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QuickVue At-Home COVID-19 Test	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Ellume COVID-19 Home Test	Ellume Limited	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Status COVID-19/Flu	Princeton BioMeditech Corp.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Simoa SARS-CoV-2 N Protein Antigen Test	Quanterix Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QuickVue SARS Antigen Test	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Clip COVID Rapid Antigen Test	Luminostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Sampinute COVID-19 Antigen MIA	Celltrion USA, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Sofia 2 Flu + SARS Antigen FIA	Quidel Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Atellica IM SARS-CoV-2 Total (COV2T)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ADEXUSDx COVID-19 Test	NOWDiagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Elecsys Anti-SARS-CoV-2	Roche Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LIAISON SARS-CoV-2 TrimericS IgG	DiaSorin, Inc.	For updated information on all products listed by the FDA use this link:

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			https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SCoV-2 Detect IgG ELISA	InBios International, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ZEUS ELISA SARS-CoV-2 IgG Test System	ZEUS Scientific, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ZEUS ELISA SARS-CoV-2 Total Antibody Test System	ZEUS Scientific, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QIArearch Anti-SARS-CoV-2 Total Test	QIAGEN, GmbH	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Elecsys Anti-SARS-CoV-2 S	Roche Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MosaiQ COVID-19 Antibody Magazine	Quotient Suisse SA	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	RapCov Rapid COVID-19 Test	ADVAITE, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SGTi-flex COVID-19 IgG	Sugentech, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Rapid COVID-19 IgM/IgG Combo Test Kit	Megna Health, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	CareStart COVID-19 IgM/IgG	Access Bio, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	QUANTA Flash SARS-CoV-2 IgG	Inova Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test	Quanterix Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MidaSpot COVID-19 Antibody Combo Detection Kit	Nirmidas Biotech, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 Self-Collected Antibody Test System	Symbiotica, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Dimension EXL SARS-CoV-2 IgG (CV2G)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Dimension Vista SARS-CoV-2 IgG (COV2G)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Atellica IM SARS-CoV-2 IgG (sCOVG)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link:

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			https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	Ortho Clinical Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SCoV-2 Detect IgM ELISA	InBios International, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Access SARS-CoV-2 IgG II	Beckman Coulter, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit	Diazyme Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	VIDAS SARS-CoV-2 IgM	bioMérieux SA	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	VIDAS SARS-CoV-2 IgG	bioMérieux SA	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	AdviseDx SARS-CoV-2 IgG II	Abbott Laboratories Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	T-Detect COVID Test	Adaptive Biotechnologies Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	WANTAI SARS-CoV-2 Ab Rapid Test	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	Ortho-Clinical Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	IDS SARS-CoV-2 IgG	Immunodiagnostic Systems Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	EliA SARS-CoV-2-Sp1 IgG Test	Phadia AB	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	UBI SARS-CoV-2 ELISA	United Biomedical, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 IgG assay	Abbott Laboratories Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette	Salofa Oy	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	RightSign COVID-19 IgG/IgM Rapid Test Cassette	Hangzhou Biotest Biotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ACON SARS-CoV-2 IgG/IgM Rapid Test	ACON Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-SeroKlir, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit	Kantaro Biosciences, LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Innovita 2019-nCoV Ab Test (Colloidal Gold)	Innovita (Tangshan) Biological Technology Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Orawell IgM/IgG Rapid Test	Jiangsu Well Biotech Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test	Xiamen Biotime Biotechnology Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	cPass SARS-CoV-2 Neutralization Antibody Detection Kit	GenScript USA Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Platelia SARS-CoV-2 Total Ab assay	Bio-Rad Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Q-Plex SARS-CoV-2 Human IgG (4 Plex)	Quansys Biosciences, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	LIAISON SARS-CoV-2 S1/S2 IgG	DiaSorin Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit	Biohit Healthcare (Hefei) Co. Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	AdviseDx SARS-CoV-2 IgM	Abbott Laboratories Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Access SARS-CoV-2 IgM	Beckman Coulter, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2	Genalyte, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	OmniPATH COVID-19 Total Antibody ELISA Test	Thermo Fisher Scientific	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	DiaSorin LIAISON SARS-CoV-2 IgM Assay	DiaSorin, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	FREND COVID-19 total Ab	NanoEntek America, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	Nirmidas Biotech, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Assure COVID-19 IgG/IgM Rapid Test Device	Assure Tech. (Hangzhou Co., Ltd)	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	MAGLUMI 2019-nCoV IgM/IgG	Shenzhen New Industries Biomedical Engineering Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BioCheck SARS-CoV-2 IgM Antibody Test Kit	BioCheck, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	BioCheck SARS-CoV-2 IgG Antibody Test Kit	BioCheck, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit	TBG Biotechnology Corp.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 ELISA pan-Ig Antibody Test	University of Arizona Genetics Core for Clinical Services	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test - Letter of Authorization	Biocan Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	BioCheck SARS-CoV-2 IgG and IgM Combo Test	BioCheck, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit	Diazyme Laboratories, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	WANTAI SARS-CoV-2 Ab ELISA	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Atellica IM SARS-CoV-2 IgG (COV2G)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	ADVIA Centaur SARS-CoV-2 IgG (COV2G)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	xMAP SARS-CoV-2 Multi-Antigen IgG Assay	Luminex Corporation	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Access SARS-CoV-2 IgG	Beckman Coulter, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Babson Diagnostics aC19G1	Babson Diagnostics, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	SARS-CoV-2 RBD IgG test	Emory Medical Laboratories	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	qSARS-CoV-2 IgG/IgM Rapid Test	Cellex Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Vibrant COVID-19 Ab Assay	Vibrant America Clinical Labs	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Healgen Scientific LLC	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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United States	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Anti-SARS-CoV-2 ELISA (IgG)	EUROIMMUN US Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	New York SARS-CoV Microsphere Immunoassay for Antibody Detection	Wadsworth Center, New York State Department of Health	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	COVID-19 ELISA IgG Antibody Test	Mount Sinai Laboratory	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	ADVIA Centaur IL6 assay	Siemens Healthcare Diagnostics Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Access IL-6	Beckman Coulter, Inc.	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
United States	Elecsys IL-6	Roche Diagnostics	For updated information on all products listed by the FDA use this link: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
Canada	Cobas SARS-CoV-2 Test	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Cobas SARS-CoV-2 Control Kit	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sw Cobas-CoV-2	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sw Cobas-CoV-2	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sw Cobas-CoV-2	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sw Cobas-CoV-2	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Taqpath COVID-19 Rt-PCR Kit	Thermo Fisher Scientific (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Taqpath COVID-19 Control Dilution Buffer	Thermo Fisher Scientific (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Applied Biosystems COVID-19 Interpretive Software	Thermo Fisher Scientific (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Taqpath COVID-19 Combo Kit	Thermo Fisher Scientific (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Taqpath COVID-19 Control Kit	Thermo Fisher Scientific (United States)	For updated information on all products listed by Health Canada use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Applied Biosystems COVID-19 Interpretive Software	Thermo Fisher Scientific (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Diaplexq Novel Coronavirus (2019-NCoV) Detection Kit	Solgent Co., Ltd. (South Korea)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Diaplexq Novel Coronavirus (2019-NCoV) Detection Kit	Solgent Co., Ltd. (South Korea)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genefinder COVID-19 Plus Realamp Kit	Osang Healthcare Co., Ltd. (South Korea)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panther Fusion SARS-CoV-2 Primer Probe Reagent	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panther Fusion SARS-CoV-2 Assay Controls	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panther Fusion Open Access Rna/dna Enzyme Reagent Cartridge	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panther Fusion Oil	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Aptiman Oil Reagent Kit	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Panther Fusion SARS-CoV-2 Internal Control-s	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panther Fusion SARS-CoV-2 Extraction Reagent-s	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panther Fusion SARS-CoV-2 Elution Buffer	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	1copy COVID-19 QPCR Multi Kit	1drop Inc. (South Korea)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Nxtag Cov Extended Panel	Luminex Molecular Diagnostics, Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Lyra SARS-CoV-2 Assay	Diagnostic Hybrids, Inc. - Also Trading As Quidel Corporation (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Bd SARS-CoV-2 Reagents For Bd Max System	Becton Dickinson And Company (Bd) (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Xpertxpress SARS-CoV-2	Cepheid (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme Franklin Three9 Real-time PCR Thermocycler	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme Sample Preparation Tray	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Transfer Pipette Pack	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Self-standing Tubes Pack	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme M1 Sample Prep Cartridge Kit For Rna 2.0	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme Fixed Volume Pipette Kit	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme SARS-CoV-2 Go-strips	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme SARS-CoV-2 Go-plates	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme SARS-CoV-2 Bulk Vials	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme Franklin Three9 Real-time PCR Thermocycler	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biomeme Franklin Three9 Real-time PCR Thermocycler	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Android Smartphone W/ Biomeme Go Mobile App	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Rugged Android Smartphone W/	Biomeme Inc (United States)	For updated information on all products listed by the TGA use this link:

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	Biomeme Go Mobile App		https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Real-time Fluorescent Rt-PCR Kit For Detecting SARS-CoV-2	Bgi Americas Corp (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 Virus Detection Diagnostic Kit (rt-qPCR Method)	Ningbo Health Gene Technologies Co., Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	ABbott Realtime SARS-CoV-2 Amplification Reagent Kit	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	ABbott Realtime SARS-CoV-2 Amplification Reagent Kit	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	ABbott Realtime SARS-CoV-2 Control Kit	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	ABbott Realtime SARS-CoV-2 Control Kit	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	ABbott Realtime SARS-CoV-2 Application Cd-rom	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	ABbott Realtime SARS-CoV-2 Application Cd-rom	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Allplex 2019-NCov Assay	Seegene Inc. (South Korea)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Spartan Cube COVID-19 System Platform	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Spartan Cube COVID-19 System - Computer	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Spartan Cube COVID-19 System - Cube	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Spartan Cube COVID-19 Test Materials	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Spartan Cube COVID-19 System - Test Kit(s)	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Spartan Cube COVID-19 System - Test Box	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Spartan Cube COVID-19 System - Swab Kit(s)	Spartan Bioscience Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Perkinelmer New Coronavirus Nucleic Acid Detection Kit	Perkinelmer, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Simplexa COVID-19 Direct Assay	Diasorin Molecular Llc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Simplexa COVID-19 Positive Control Pack	Diasorin Molecular Llc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Triplelock SARS-CoV-2 Test Strips	Precision Biomonitoring Inc. (Canada)	For updated information on all products listed by the TGA use this link:

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			https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Anti-SARS-CoV-2 Elisa (IgG)	Euroimmun Medizinische Labordiagnostika Ag (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Aries SARS-CoV-2 Assay	Luminex Corporation (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biofire COVID-19 Test	Biofire Defense (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Biofire COVID-19 Test External Control Kit (+)	Biofire Defense (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Argene SARS-CoV-2 R-gene	Biomerieux Sa (France)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Qiasat-dx Analyzer 1.0	Qiagen GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Qiasat-dx Operational Module	Qiagen GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Qiasat-dx Respiratory SARS-co V-2 Panel	Qiagen GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Qiasat-dx Analytical Module	Qiagen GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	Ortho-Clinical Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator	Ortho-Clinical Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total Controls	Ortho-Clinical Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Liaison Control SARS-CoV-2 S1/s2 IgG	Diasorin Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Liaison SARS-CoV-2 S1/s2 IgG	Diasorin Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Reagent Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Reagent Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Control Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Calibrator Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Preci Control Anti-SARS-CoV-2	Roche Diagnostics GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sofia SARS Antigen Fia	Quidel Corporation (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sofia SARS Antigen Fia	Quidel Corporation (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Ftd SARS-CoV-2	Fast Track Diagnostics Luxembourg S.A.R.L. (Luxembourg)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Filmarray Respiratory Panel 2.1 (rp2.1)	Biofire Diagnostics, LLC. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Lyra Direct SARS-CoV-2 Assay	Diagnostic Hybrids, Inc. - Also Trading As Quidel Corporation (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Platelia SARS-CoV-2 Total AB	Bio-Rad (France)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Platelia SARS-CoV-2 Total AB	Bio-Rad (France)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	SARS-CoV-2 IgG Reagent Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Reagent Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Control Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	SARS-CoV-2 IgG Calibrator Kit	Abbott Laboratories Diagnostics Division (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Bkit Virus Finder COVID-19	Hyris Ltd (Great Britain)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Bcube 2.0	Hyris Ltd (Great Britain)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	16wells Cartridges	Hyris Ltd (Great Britain)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Advia Centaur SARS-CoV-2 Total (cov2t)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Advia Centaur SARS-CoV-2 Total (cov2t)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Advia Centaur SARS CoV-2 Total Quality Control (cov2t Qc)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Atellica Im SARS-CoV-2 Total (cov2t)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Atellica Im SARS-CoV-2 Total (cov2t)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Atellica Im SARS-CoV-2-total Quality Control (cov2t Qc)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Dimension Vista SARS-CoV-2 Total Antibody (cov2t)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Dimension Vista/dimension Exl SARS-CoV-2 Total Antibody Quality Control (cov2t/cv2t Pos/neg)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Dimension Vista/dimension Exl SARS-CoV-2 Total Antibody Calibrator (cov2t Cal/cv2t Cal)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Dimension Vista/dimension Exl SARS-CoV-2 Total Antibody Calibrator (cov2t Cal/cv2t Cal)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Dimension Exl SARS-CoV-2 Total Antibody (cv2t) Assay	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Dimension Vista/dimension Exl SARS-CoV-2 Total Antibody Quality Control (cov2t/cv2t Pos/neg)	Siemens Healthcare Diagnostics Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Anti-SARS-CoV-2 IgG Elisa Kit	Diagnostics Biochem Canada Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Alinity M SARS-CoV-2 Amp Kit	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Alinity M SARS-CoV-2 Ctrl Kit	Abbott Molecular Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Aptima SARS-CoV-2 Controls Kit	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Aptima SARS-CoV-2 Assay Kit	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Aptima Multitest Swab Specimen Collection Kit For SARS-CoV-2 Specimen Collection	Hologic, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Bd Veritor System For Rapid Detection Of SARS-CoV-2	Becton Dickinson And Company (Bd) (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Bd Veritor System For Rapid Detection Of SARS-CoV-2	Becton Dickinson And Company (Bd) (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html

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Canada	Anti-SARS-CoV-2 Total Antibody (ab) Elisa Kit	Diagnostics Biochem Canada Inc. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Id Now COVID-19	Abbott Diagnostics Scarborough, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Id Now COVID-19 Control Swab Kit	Abbott Diagnostics Scarborough, Inc. (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panbio COVID-19 AG Rapid Test Device (nasopharyngeal)	Abbott Rapid Diagnostics Jena GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Cobas SARS-CoV-2 & Influenza A/b	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Cobas SARS-CoV-2 & Influenza A/b Control Kit	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sw Cobas Scov2-flua/b Asap V 10.1.0	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Sw Cobas Scov2-flua/b Asap V 11.1.0	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount Clinical Auto Rna Isolation Kit	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount E-32 Auto Purification Instrument	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount COVID-19 Rt-qPCR Assay Kit	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link:

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			https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount Clinical Advanced Rna Isolation Kit	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount Q-16, FlxI, Real Time QPCR Equip Set	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount Q-16, FlxI, Real Time QPCR Equip Set	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Genecount Q-16, FlxI, Real Time QPCR Equip Set	Luminultra Technologies Ltd. (Canada)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Cobas Liat SARS-CoV-2 & Influenza A/b Quality Control Kit	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Cobas SARS-CoV-2 & Influenza A/b	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Cobas Liat SARS-CoV-2 & Influenza A/b Script Software Version 1.0	Roche Molecular Systems, Inc (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Xpert Xpress SARS-CoV-2/flu/RSV	Cepheid (United States)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Canada	Panbio COVID-19 AG Rapid Test Device (nasal)	Abbott Rapid Diagnostics Jena GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html
Japan	2019-nCoV Fluorescence	Sysmex Corporation	For updated information on all products listed by the TGA use this link:

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	Detection Real-time RT-PCR kit		https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Loopamp Novel Coronavirus 2019 (SARS-CoV-2) Detection Kit	Eiken Chemical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	cobas SARS-CoV-2	Roche Diagnostics K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	TaqPath Real Time PCR Reagent Kit for SARS-CoV-2	Life Technologies Japan Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Xpert Xpress SARS-CoV-2 'Cepheid'	Beckman Coulter, Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	MEBRIGHT SARS-CoV-2 Kit	MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	FilmArray Respiratory Panel 2.1	bioMérieux Japan Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	GENECUBE SARS-CoV-2	TOYOBO CO., LTD.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html

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Japan	TRCReady SARS-CoV-2	TOSOH CORPORATION	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	SmartAmp SARS-CoV-2	K.K. DNAFORM	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Aptima SARS-CoV-2	Hologic Japan, Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Ampdirect 2019-nCoV Detection Kit	SHIMADZU CORPORATION	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	i-densy Pack SARS-CoV-2	ARKRAY Factory, Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	ID NOW COVID-19	Abbott Diagnostics Medical Co., Ltd	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	GENECUBE HQ SARS-CoV-2	TOYOBO CO., LTD.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	SGNP nCoV/Flu PCR Detection Kit	SUDx-Biotec Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html

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Japan	Takara SARS-CoV-2 Direct PCR detection kit	Takara Bio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	cobas SARS-CoV-2 & Flu A/B	Roche Diagnostics K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Illumina COVIDSeq Test	Illumina K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	TaqPath SARS-CoV-2 Real Time PCR Reagent Kit HT	Life Technologies Japan Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	TRCReady SARS-CoV-2 i	TOSOH CORPORATION	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Simprova SARS-CoV-2 Detection Kit	Eiken Chemical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Takara SARS-CoV-2 & Flu Direct PCR detection kit	Takara Bio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Smart Gene SARS-CoV-2	MIZUHO MEDY Co.,Ltd	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html

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Japan	Alinity m system SARS-CoV-2	Abbott Japan LLC	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	cobas Liat SARS-CoV-2 & Flu A/B	Roche Diagnostics K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Xpert Xpress SARS-CoV-2/Flu‘Cepheid’	Beckman Coulter, Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	DetectAmp SARS-CoV-2 RT-PCR Kit	Sysmex Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	DELBio Dagane G1 SARS-CoV-2 Detection Kit	DELTA ELECTRONICS (JAPAN), INC.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	SGNP nCoV PCR detection kit	SUDx-Biotec Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Swiftgene SARS-CoV-2 KAINOS	KAINOS Laboratories, Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	ESPLINE SARS-CoV-2	Fujirebio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html

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Japan	Lumipulse G SARS-CoV-2 Ag	Fujirebio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	QuickNavi-COVID19 Ag	Denka Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	ImunoAce SARS-CoV-2 Capilia SARS-CoV-2	TAUNS LABORATORIES, INC.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Lumipulse Presto SARS-CoV-2 Ag	Fujirebio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	HISCL SARS-CoV-2 Ag Assay Kit	Sysmex Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	SARS-CoV-2 Antigen Rapid Test Kit Rapiim SARS-CoV-2-N PRT-C2N01A	CANON MEDICAL SYSTEMS CORPORATION	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	LumiraDx SARS-CoV-2 Ag Test Strip	LumiraDx Japan Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	PanbioTM COVID-19 Ag Rapid Test Device(NASOPHARYN GEAL)/ PanbioTM	Abbott Diagnostics Medical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html

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	COVID-19 Ag Rapid Test Device(NASAL)		
Japan	BD Veritor System for Rapid Detection of SARS-CoV-2	Becton, Dickinson and Company	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	PRORAST SARS-CoV-2 Ag ADTest SARS-CoV-2	ADTEC Corporation/LSI Medience Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	SARS-CoV-2 Rapid Antigen Test	Roche Diagnostics K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	FUJI DRI-CHEM IMMUNO AG HANDY COVID-19 Ag	FUJIFILM Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Sofia SARS Antigen FIA	Quidel Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Quick Chaser Auto SARS-CoV-2	MIZUHO MEDY Co.,Ltd	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	FUJI DRI-CHEM IMMUNO AG CARTRIDGE COVID-19 Ag	MIZUHO MEDY Co.,Ltd	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	ALSONIC COVID-19 Ag	Alfresa Pharma Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html

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			and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	KBM LineCheck nCoV (Stick Type)	KOHJIN BIO CO., LTD.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Elecsys SARS-CoV-2 Antigen	Roche Diagnostics K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	COVID-19 and Influenza A+B Antigen Combo Test (NichireiBio)	Nichirei Biosciences Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	ImmunoArrow SARS-CoV-2	TOYOBO CO., LTD.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	VITROS SARS-CoV-2 Antigen	ORTHO-CLINICAL DIAGNOSTICS K.K.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Check MR-COV19	ROHTO Pharmaceutical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Lumipluse Flu-A&B	Fujirebio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	GENECUBE FluA/B	TOYOBO CO., LTD	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html

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			and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Lumipulse Presto Flu-A&B	Fujirebio Inc.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	HISCL IFN-λ3 Assay Kit	Sysmex Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Loopamp Influenza B virus Detection Kit	Eiken Chemical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Simprova Influenza A virus Detection Kit	Eiken Chemical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	Simprova Influenza B virus Detection Kit	Eiken Chemical Co., Ltd.	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Japan	HISCL Influenza Assay Kit	Sysmex Corporation	For updated information on all products listed by the TGA use this link: https://www.mhlw.go.jp/stf/newpage_11332.html and https://www.pmda.go.jp/english/about-pmda/0002.html
Australia	Abbott RealTime SARS-CoV-2	Abbott Australasia Pty Ltd Molecular Division	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	2019-nCoV Ab Test (Colloidal Gold)	Innovita (Tangshan) Biological Technology Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	2019-n-CoV IgG/IgM Rapid Test Cassette	Hangzhou Alltest Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	2019-nCoV/COVID-19 IgG/IgM Rapid Test Device	Hangzhou Realy Tech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Access SARS-CoV-2 IgG Antibody Test	Beckman Coulter Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	ADVIA Centaur® SARS-CoV-2 Total (COV2T) assay	Siemens Healthcare Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Alinity m SARS-CoV-2 AMP Kit	Abbott Molecular Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Allplex™ 2019-nCoV Assay	Seegene Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Allplex™ SARS-CoV-2 Assay	Seegene Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Anti-SARS-CoV-2 ELISA (IgA)	EUROIMMUN Medizinische Labordiagnostika AG (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Anti-SARS-CoV-2 ELISA (IgG)	EUROIMMUN Medizinische Labordiagnostika AG (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Anti-SARS-CoV-2 NCP ELISA (IgG)	EUROIMMUN Medizinische	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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		Labordiagnostika AG (Germany)	
Australia	Anti-SARS-CoV-2 NCP ELISA (IgM)	EUROIMMUN Medizinische Labordiagnostika AG (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Aptima® SARS-CoV-2 Assay	Hologic Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Aridia COVID-19 Real-Time PCR Test	CTK Biotech Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Atellica® IM SARS-CoV-2 Total (COV2T) assay	Siemens Healthcare Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	AtomoRapid™ COVID-19 IgM/IgG Antibody Test	Atomo Diagnostics Limited (Australia)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	AusDiagnostics respiratory virus panel (including SARS-CoV-2) test	AusDiagnostics Pty Ltd (Australia)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	BD SARS-CoV-2 Reagents for BD MAX™ System	Becton Dickinson and Company (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson and Company (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Bio-Core 2019-nCoV Real Time PCR Kit	BioCore Co Ltd (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	BioFire Respiratory Panel 2.1 plus (RP2.1plus)	BioFire Diagnostics LLC	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	CareStart™ COVID-19 Antigen	Access Bio Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	CareStart™ COVID-19 MDx RT-PCR	Access Bio Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test kit	Cellex Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	cobas® SARS-CoV-2	Roche Molecular Systems Inc (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID 19 IgG/IgM Rapid Test Cassette	Zhejiang Orient Gene Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 (SARS-CoV-2) Nucleic Acid Test kit	Wuhan EasyDiagnosis Biomedicine Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 Coronavirus Real Time PCR Kit	Jiangsu Bioperfectus Technologies Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Hangzhou Biotest Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Hangzhou Clongene Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Healgen Scientific Limited Liability	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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		Company (United States Of America)	
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Newscen Coast Bio-Pharmaceutical Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Zhejiang Orient Gene Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Cassette	Zhejiang Orient Gene Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Kit	Nantong Egens Biotechnology Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 IgG/IgM Rapid Test Kit	Zhongshan Chuangyi Biochemical Engineering Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)	Da An Gene Co Ltd of Sun Yat-sen University (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)	Zhuhai Livzon Diagnostics Inc (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow)	Zhuhai Livzon Diagnostics Inc (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)	Siemens Healthcare Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Dimension Vista® SARS-CoV-2 Total antibody assay (COV2T)	Siemens Healthcare Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	EasyNat Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	Ustar Biotechnologies (Hangzhou) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	EasyScreen™ SARS-CoV-2 Detection Kit	Genetic Signatures Ltd (Australia)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Elecsys Anti-SARS-CoV-2	Roche Diagnostics GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	EURORealTime SARS-CoV-2	EUROIMMUN Medizinische Labordiagnostika AG (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	GB SARS-CoV-2 Real Time RT-PCR	General Biologicals Corp (Taiwan)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	GenBody COVID-19 IgM/IgG	GenBody Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	GeneFinder™ COVID-19 Plus RealAmp Kit	OSANG Healthcare Co Ltd (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	genesig® Real-Time PCR Coronavirus COVID-19	Primer Design Limited (United Kingdom)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	IAstat-Dx® Respiratory SARS-CoV-2 Panel	Qiagen GmbH	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	iFlash-SARS-CoV-2 IgG	Shenzhen YHLO Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	iFlash-SARS-CoV-2 IgM	Shenzhen YHLO Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	InnoScreen™ COVID-19 IgG/IgM Rapid Test	Innovation Scientific Pty Ltd (Australia)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	LabGun™ COVID-19 RT-PCR Kit	Labgenomics Co Ltd (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	LIAISON® SARS-CoV-2 IgM	DiaSorin SpA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	LIAISON® SARS-CoV-2 S1/S2 IgG	DiaSorin SpA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Logix Smart™ Coronavirus Disease 2019 (COVID-19) Kit	Co-Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	NeuMoDx™ SARS-CoV-2 Assay	NeuMoDx Molecular Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	NOVA Test® COVID-19 IgG/IgM Antibody Test (Colloidal Gold)	Atlaslink Beijing Technology Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	Hangzhou Laihe Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Sansure Biotech Inc (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes)	Shanghai ZJ Bio-Tech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	Shanghai Fosun Long March Medical Science Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	NowCheck COVID-19 Antigen Test	BioNote Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	NTBIO One Step Rapid Test - COVID-19 IgG/IgM Antibody Test	NTBIO Diagnostics Inc (Canada)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	OnSite COVID-19 IgG/IgM Rapid Test	CTK Biotech Inc (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	Panther Fusion® SARS-CoV-2 Assay (Panther Fusion® System)	Hologic Inc (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	PCL COVID19 IgG/IgM Rapid Gold	PCL Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	Suzhou Sym-Bio Lifescience Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Platelia SARS-CoV-2 Total Ab	Bio-Rad (France)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	PowerChek™ 2019-nCoV Real-time PCR Kit	Kogene Biotech Co Ltd (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2	BGI Europe A/S (Denmark)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 Antibody Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 Antibody Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 Antibody Test (Lateral Flow Method)	Guangzhou Wondfo Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 IgG Kit	Abbott Ireland Diagnostic Division (Ireland)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	SARS-CoV-2 IgM Kit	Abbott Ireland Diagnostic Division (Ireland)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 IgM/IgG Antibody Rapid Test	Qingdao Hightop Biotech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 IgM/IgG Antibody Test Kit	Wuhan EasyDiagnosis Biomedicine Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-COV-2 R-GENE®	Biomerieux SA (France)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 RT-qPCR Reagent Kit	Wallac Oy (Finland)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Simplexa™ COVID-19 Direct	DiaSorin Molecular LLC (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Sofia® SARS Antigen FIA	Quidel Corporation (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	TaqPath COVID-19 Combo Kit	Life Technologies Corporation (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Veri-Q PCR 316 COVID-19 Detection Kit	MiCoBioMed Co Ltd (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	CerTest Biotec SL (Spain)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit	CerTest Biotec SL (Spain)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VIDAS® SARS-COV-2 IgG	Biomerieux SA (France)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VIDAS® SARS-COV-2 IgM	Biomerieux SA (France)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	ViroKey™ SARS-CoV-2 RT-PCR Test v2.0	Vela Operations Singapore Pte Ltd (Singapore)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total	Ortho-Clinical Diagnostics (United Kingdom)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VivaDiag™ COVID-19 IgM/IgG Rapid Test	VivaCheck Biotech (Hangzhou) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VivaDiag™ COVID-19 IgM/IgG Rapid Test	VivaChek Biotech (Hangzhou) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VivaDiag™ COVID-19 IgM/IgG Rapid Test	VivaChek Biotech (Hangzhou) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Wantai SARS-CoV-2 Ab Rapid Test kit	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Xpert® Xpress SARS-CoV-2	Cepheid (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	SARS-CoV-2 Antigen Rapid Test Kit	BIOHIT HealthCare (Hefei) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	InnoScreen COVID-19 Antigen Rapid Test Device	Innovation Scientific Pty Ltd (Australia)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	DirectDetect™ SARS-CoV-2 Detection Kit	Coyote Bioscience Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	ID NOW COVID-19	Abbott Diagnostics Scarborough Inc also d/b/a Alere Scarborough Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Panbio™ COVID-19 Ag Rapid Test Device	Abbott Rapid Diagnostics Jena GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	STANDARD™ Q COVID-19 Ag Test	SD Biosensor Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Wantai SARS-CoV-2 Ab ELISA	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 Antigen Quantitative Assay Kit (Enzyme-linked Immunoassay)	BIOHIT HealthCare (Hefei) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold Metho	BIOHIT HealthCare (Hefei) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson and Company (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes)	Shanghai ZJ Bio-Tech Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 IgM Kit	Abbott Ireland Diagnostic Division (Ireland)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	CareStart™ COVID-19 Antigen	Access Bio Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	GSP®/DELFI® Anti-SARS-CoV-2 IgG kit	Wallac Oy (Finland)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	Ustar Biotechnologies (Hangzhou) Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 Antigen Rapid Test Device	Assure Tech (Hangzhou) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Atomo Covid-19 Antigen Test	Access Bio Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG	Ortho-Clinical Diagnostics (United Kingdom)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 Antigen Rapid Test Kit	BIOHIT HealthCare (Hefei) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 Antigen Rapid Test Cassette	BTNX Inc (Canada)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test	Xiamen Biotime Biotechnology Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VivaDiag™ SARS-CoV-2 Ag Rapid Test	VivaChek Biotech (Hangzhou) Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 Rapid Antigen Test	SD Biosensor Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Anti-SARS-CoV-2 QuantiVac ELISA (IgG)	EUROIMMUN Medizinische Labordiagnostika AG (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay	Seegene Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	RT-PCR IVD MEDICAL DEVICE FOR 2019 NOVEL CORONAVIRUS (SARS-COV-2)	HA TECH PTY LTD (Australia)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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	NUCLEIC ACID DETECTION		
Australia	cobas® SARS-CoV-2 & Influenza A/B	Roche Molecular Systems Inc (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	GenBody COVID-19 Ag	GenBody Inc (Korea - Republic of)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	PKamp™ Respiratory SARS-CoV-2 RT-PCR Panel	Suzhou Sym-Bio Lifescience Co Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	OnSite® COVID-19 Ag Point of care test / Aria® COVID-19 Ag Rapid Test	CTK Biotech Inc (USA)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Resolute 2.0 SARS CoV-2 Detection Kit	Accelerate Technologies Pte Ltd (DxD Hub) (Singapore)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	ADVIA Centaur® SARS-CoV-2 IgG (sCOVG) assay	Siemens Healthcare Diagnostics Inc	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Atellica® IM SARS-CoV-2 IgG (sCOVG) assay	Siemens Healthcare Diagnostics Inc	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	SARS-CoV-2 IgG II Quant Kit	Abbott Ireland Diagnostic Division	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Xpert® Xpress SARS-CoV-2/Flu/RSV	Cepheid Holdings Pty Ltd	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	Panbio™ COVID-19 Ag Rapid Test Device (Nasal)	Abbott Rapid Diagnostics Jena GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen	Ortho-Clinical Diagnostics (United Kingdom)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	COVID-19 Real-Time PCR kit (HBRT-COVID-19)	Chaozhou Hyribio Biochemistry Ltd (China)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Dimension Vista® SARS-CoV-2 IgG Assay (CV2G)	Siemens Healthcare Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Dimension EXL SARS-CoV-2 IgG Assay (CV2G)	Siemens Healthcare Diagnostics Inc (United States Of America)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Elecsys Anti-SARS-CoV-2 S	Roche Diagnostics GmbH (Germany)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Enzywell SARS-CoV-2 IgA	Diesse Diagnostica Senese SPA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Chorus SARS-CoV-2 IgM	Diesse Diagnostica Senese SPA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Chorus SARS-CoV-2 IgG	Diesse Diagnostica Senese SPA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Chorus SARS-CoV-2 IgA	Diesse Diagnostica Senese SPA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia

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Australia	Enzywell SARS-CoV-2 IgM	Diesse Diagnostica Senese SPA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Enzywell SARS-CoV-2 IgG	Diesse Diagnostica Senese SPA (Italy)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2 (2 gene)	BGI Europe A/S (Denmark)	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Australia	BIOCREDIT COVID-19 Ag	RapiGEN Inc	For updated information on all products listed by the TGA use this link: https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia
Singapore	VereCoV™ Detection Kit	Veredus Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	abTES™ COVID-19 qPCR I Kit	AITbiotech Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Real-Time PCR Assay for the Detection of SARS-CoV-2 Virus	DSO National Laboratories	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Cobas® SARS-CoV-2	Roche Diagnostics Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ProTect™ COVID-19 RT-qPCR Kit	JN Medsys Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	TaqPath™ COVID-19 Combo Kit	Life Technologies Holdings Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	Novel Coronavirus (2019-nCoV) RNA kit (Isothermal Amplification- Real Time Fluorescence Assay)	Biowalker Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Cepheid® Xpert® Xpress SARS-CoV-2	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MiRXES FORTITUDE KIT 2.0	MiRXES Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Acu-Corona™ 2.0	Acumen Research Laboratories	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VitaPCR™ SARS-CoV-2 Assay	Credo Diagnostics Biomedical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Abbott RealTime SARS-CoV-2 assay	Abbott Laboratories (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Seegene Allplex™ 2019-nCoV Assay	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Acu-Corona 3.0	Acumen Research Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ViroKey SARS-CoV-2 RT-PCR Test	Vela Operations Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	PerkinElmer Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BioWalker SARS-CoV-2 Assay	BioWalker Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Sansure Biotech Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit	Medicell Pharmaceutical (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	BGI Health (SG) Company Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Fortitude™ Kit 2.1	Diagnostics Development Hub (DxD)	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Allplex 2019-nCoV Assay	Genomax Technologies Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BioWalker SARS-CoV-2 Assay 2.0	BioWalker Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	Tanglin Cardiology Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BD SARS-CoV-2 Reagents for BD MAX™ System	Becton Dickinson Holding Ptd Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Liferiver Novel Coronavirus (2019-	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link:

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	nCoV) Real Time Multiplex RT-PCR Kit		https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Luminex NxTAG® CoV Extended Panel Assay	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MiRXES Fortitude Kit 2.1	MiRXES Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BioFire® Respiratory Panel 2.1 (RP2.1)	BioMérieux Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	GeneFinder™ COVID-19 Plus RealAmp Kit	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	altona Diagnostics RealStar™ SARS-CoV-2 RT-PCR Kit 1.0	SDT Molecular Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	AMT RESOLUTE 1.0	AMT Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Fosun Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	Novena Global Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	FTD™ SARS-CoV-2	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	QIAstat-Dx® Respiratory SARS-CoV-2 Panel	Qiagen Singapore Pte. Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VereRT™ COVID-19 PCR Kit	Veredus Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link:

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			https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Fosun Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	XIN Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VitaPCR™ SARS-CoV-2 Gen 2 Assay	Credo Diagnostics Biomedical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Luminex ARIES® SARS-CoV-2 Assay	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Hologic Aptima® SARS-CoV-2 assay	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Accelerate Technologies Resolute 2.0 assay	Accelerate Technologies Pte Ltd (DxD Hub)	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	genesig® Real-Time PCR COVID-19 (Swab Use)	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Seegene Allplex™ SARS-CoV-2 Assay	Andaman Medical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	AccuraDTect SARS-CoV-2 RT-qPCR Kit	EMERGO by UL	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ViroKey™ SARS-CoV-2 RT-PCR Test v2.0	Vela Operations Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Novel Coronavirus (2019-nCoV) Nucleic	Biotrilance Pte Ltd	For updated information on all products listed by the HSA use this link:

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	Acid Detection Kit (PCR-Fluorescence Probing)		https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ProTect COVID-19 RT-qPCR Kit 2.0	JN Medsys Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	AMT Resolute 2.0 assay	AMT Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	TaqPath™ COVID 19 CE IVD RT PCR Kit	Life Technologies Holdings Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BioFire® Respiratory Panel 2.1 plus (RP2.1plus)	BioMérieux Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	genesig® Real-Time PCR COVID-19 (Swab Use)	Gaia Science Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VereRT™ ZeroPrep™ COVID-19 PCR Kit	Veredus Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection kit	Link Trust Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Illumina COVIDSeq Test	Illumina Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	CORO Real-Time RT-PCR SARSCoV-2	INEX Innovate Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BioA SARS-CoV-2 Real-Time RT-PCR Kit v1.0	BioAcumen Global Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	TEPAT 1.0 SARS-CoV-2 Multiplex RT-PCR Kit	Cellbae Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Abbott Alinity m SARS-CoV-2 AMP Kit	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	QuikPath SARS-CoV-2 Isothermal RT-PCR Kit	QuikPath Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Satugen Solo	Acumen Research Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Acu-Corona Solo	Acumen Research Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	Biorodi Company Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	Anomalous Materials Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VereCoV™ OneMix Detection Kit	Veredus Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	InnoCare SARS-CoV-2 RT-PCR Kit	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MiRXES Fortitude SARS-CoV-2 & FluA/B Test	MiRXES Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	DirectDetect SARS-CoV-2 Detection Kit	IceSing Bioscience Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Shimadzu Ampdirect 2019-nCoV Detection Kit	Shimadzu (Asia Pacific) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Cepheid® Xpert® Xpress SARS-CoV-2/Flu/RSV Assay	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MiRXES Fortitude Kit 3.0	MiRXES Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	cobas® Liat SARS-CoV-2 & Influenza A/B	Roche Diagnostics Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Acu-Corona Duplex	Acumen Research Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Satugen Duplex	Acumen Research Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Standard Q COVID-19 Ag Test	Xentific Labs Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	FaStep COVID-19 Antigen Rapid Test	Alcotech Pte Ltd	For updated information on all products listed by the HSA use this link:

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	Device (Nasopharyngeal/ Oropharyngeal Swab)		https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SAVANT™ New Coronavirus (SARS- CoV-2) N Protein Detection Kit (Fluorescence Immunochromatogra- phy)	Hi-Beau Group	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BD Veritor™ System for Rapid Detection of SARS-CoV-2	Becton Dickinson Holding Ptd.Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Standard Q COVID-19 Ag Test	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Sofia SARS Antigen FIA	Quantum Technologies Global Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	COVID-19 Antigen Rapid Test Kit	Jian Yuan Holdings Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Camtech COVID-19 Antigen Rapid Test	Camtech Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	GenBody COVID-19 Ag	Unison Collaborative Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	GenBody COVID-19 Ag	Tigermed Asia Pacific Private Limited	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	ESPLINE® SARS-CoV-2	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)	Unison Collaborative Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BIOCREDIT COVID-19 Ag	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SARS-CoV-2 Rapid Antigen Test	Roche Diagnostics Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VivaDiag™ SARS-CoV-2 Ag Rapid Test	Everest Links Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SGTi-flex COVID-19 Ag	Veredus Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SGTi-flex COVID-19 Ag	Zyfas Pharma Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	GenBody COVID-19 Ag	Amaquest Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	GENEDIA W COVID-19 Ag	Andaman Medical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Biolidics Limited	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	Panbio™ COVID-19 Ag Rapid Test Device (Nasal)	Unison Collaborative Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SGTi-flex COVID-19 Ag	Amaquest Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	Ortho Clinical Diagnostics	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	COVID-19 Antigen Test	SG Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Dynamiker SARS-CoV-2 Ag Rapid Test	Deel Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	V-CODE ENCODE SARS-COV-2 Antigen Rapid Test Device	HealthGroup Medical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Vstrip COVID-19 Antigen Rapid Test	Hermes-Epitek Corporation Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)	SG Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	CerTest SARS-CoV-2	BioMedix Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	CLUNGENE® COVID-19 Antigen Rapid Test Cassette	Xentific Labs Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Dynamiker SARS-CoV-2 Ag Rapid Test	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Novel Coronavirus 2019 n-CoV Antigen Test (Colloidal Gold)	Sailfish Innovations Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Hangzhou Alltest COVID-19 Antigen Rapid Test (Nasopharyngeal Swab)	SkyQuest Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Liming Bio StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test	SK BIOTECH PTE LTD	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ARISTA™ COVID-19 Antigen Rapid Test	ARISTA Biotech Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens ADVIA Centaur® SARS-CoV-2 Antigen (CoV2Ag)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens Atellica® IM SARS-CoV-2 Antigen (CoV2Ag)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Standard Q COVID-19 Ag Test (Nasal Swab)	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Roche Elecsys SARS-CoV-2 Antigen	Roche Diagnostics Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link:

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			https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	CLINITEST Rapid COVID-19 Antigen Test	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VivaDiag™ SARS-CoV-2 IgM/IgG Rapid Test	Everest Links Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit also marketed as Biolidics 2019-nCoV IgG/IgM Detection Kit	Biolidics Limited	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Wondfo 2019-nCoV Antibody Test (Lateral Flow Method)	SkyQuest Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Camtech COVID-19 IgM/IgG	Camtech Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	DiagnoSure COVID-19 IgG/ IgM Rapid Test Cassette	Grit Overseas Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Shanghai LiangRun LionRun Diagnostic Kit for Antibody IgM-IgG of Novel Coronavirus COVID-19	Veredus Laboratories Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	INNOVITA 2019-nCoV Ab Test (Colloidal Gold)	Bioforge Solutions Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Wondfo 2019-nCoV Antibody Test (Lateral Flow Method)	Bioforge Solutions Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Abbott SARS-CoV-2 IgG – ARCHITECT assay	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Roche Elecsys Anti-SARS-CoV-2	Roche Diagnostics Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack	Ortho Clinical Diagnostics	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test	MP Biomedicals Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	INNOVITA 2019-nCoV Ab Test (Colloidal Gold)	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit	Genscript Biotech (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Xiamen Boson Rapid 2019-nCoV IgG/IgM Combo Test Card	Trans Sahara Corporation Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	EDI™ Novel Coronavirus COVID-19 IgM ELISA Kit	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	HealthGroup Medical V-CODE Sars-CoV-2 (COVID-19) IgG/IgM Rapid Test	Healthgroup Medical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	i-Test COVID -19 IgM/IgG Antibody Rapid Test (Colloidal Gold)	I-Test Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	INNOVITA 2019-nCoV Ab Test (Colloidal Gold)	Ying Assets Management Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ABBOTT Alinity i SARS-CoV-2 IgG	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BIOSYNEX COVID-19 BSS	COBS Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)	Euroimmun (South East Asia) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	2019-nCoV IgG/IgM Rapid Test	SPD Scientific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SARS-CoV-2 Antibody Test Strip	Trident Pharm Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	2019-nCoV/COVID-19 IgG/IgM Rapid Test Device	Sinch Medical Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgA)	Euroimmun (South East Asia) Pte. Ltd.	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Genrui Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal Gold)	Transmedic Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens Atellica® IM SARS-CoV-2 Total (COV2T)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens ADVIA Centaur® SARS-CoV-2 Total (COV2T)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	Ortho Clinical Diagnostics	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	2019-nCoV IgG/IgM Rapid Test Cassette	Alcotech Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	RightSign COVID-19 IgG/IgM Rapid Test Cassette	Unison Collaborative Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Biorad Platelia SARS-CoV-2 Total Ab	Bio-Rad Laboratories (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ACCESS SARS-CoV-2 IgG	Beckman Coulter Singapore Pte Ltd	For updated information on all products listed by the HSA use this link:

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Singapore	Panbio™ COVID-19 IgG/IgM Rapid Test Device	Unison Collaborative Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	RAS Rapid Test - 2019-nCov IgG/IgM Rapid Test	RAS Pharma and Biochem Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Smart COVID-19 IgM-IgG Rapid Diagnostic Test	Cell ID Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	RAPIT COVID-19 IgM/IgG Test Kit	Restalyst Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Hangzhou Lysun 2019-nCoV IgG/IgM Rapid Test Device	Genomax Technologies Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens Atellica® IM SARS-CoV-2 IgG (COV2G)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens ADVIA Centaur® SARS-CoV-2 IgG (COV2G)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	EUROIMMUN Anti-SARS-CoV-2 NCP ELISA (IgG)	EUROIMMUN (SOUTH EAST ASIA) PTE. LTD.	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Restalyst COVID19N-REAAD™ Anti-SARS-CoV-2 Nucleocapsid Protein IgG ELISA	Restalyst Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Singapore	MAGLUMI 2019-nCoV IgG (CLIA)	Nova Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MAGLUMI 2019-nCoV IgM (CLIA)	Nova Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	FaStep COVID-19 IgG/IgM Rapid Test Device	Alcotech Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Abbott ARCHITECT SARS-CoV-2 IgM	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ABBOTT Alinity i SARS-CoV-2 IgM	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VIDAS® SARS-COV-2 IgG	bioMérieux Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	VIDAS® SARS-COV-2 IgM	bioMérieux Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Ansh Labs SARS-CoV2 IgM ELISA (μ-Capture)	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Ansh Labs SARS-CoV2 IgG ELISA	All Eights (Singapore) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Roche Elecsys Anti-SARS-CoV-2 S	Roche Diagnostics Asia Pacific Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ichroma™ COVID-19 Ab	ZMC Technologies Pte Ltd	For updated information on all products listed by the HSA use this link:

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Singapore	SARS-CoV-2 IgG (Electrochemiluminescence Immunoassay)	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	SARS-CoV-2 IgM (Electrochemiluminescence Immunoassay)	Biomed Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	ACCESS SARS-CoV-2 IgM	Beckman Coulter Singapore Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	MAGLUMI SARS-CoV-2 S-RBD IgG (CLIA)	Nova Diagnostics Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens Atellica® IM SARS-CoV-2 IgG (sCOVG)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Siemens ADVIA Centaur® SARS-CoV-2 IgG (sCOVG)	Siemens Healthcare Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Abbott ARCHITECT SARS-CoV-2 IgG II Quant	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	Abbott Alinity i SARS-CoV-2 IgG II Quant	Abbott Laboratories (S) Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	BreFence Go COVID-19 Breath Test System	Breathonix Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
Singapore	TracieX Breathalyzer	Silver Factory Technology Pte Ltd	For updated information on all products listed by the HSA use this link: https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation

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Brazil	Novo kit de teste de anticorpos IgM /IgG para coronavirus (2019-nCoV) (ouro coloidal)	1000MEDIC DISTRIBUIDORA IMPORTADORA EXPORTADORA DE MEDICAMENTOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Família SARS-CoV-2 IgG	ABBOTT LABORATÓRIOS DO BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Família Abbott RealTime SARS-CoV-2 EUA	ABBOTT LABORATÓRIOS DO BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Família Abbott RealTime SARS-CoV-2	ABBOTT LABORATÓRIOS DO BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Família Abbott RealTime SARS-CoV-2	ABS COMERCIO E IMPORTACAO LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	COVID-19 IgG/IgM LF	ADVAGEN BIOTECH LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	CORONAVIRUS COVID -19 IgG/IgM Teste Rapido	ALAMAR TECNO CIENTÍFICA LTDA - CNPJ	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Panbio COVID-19 IgG/IgM Rapid Test Device	Alere S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	BasePoint COVID-19 IgG/IgM	Alere S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Quick PROFILE COVID-19 IgG/IgM Test Card	ARGOSLAB DISTRIBUIDORA DE	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus

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		PRODUTOS PARA LABORATÓRIOS LTDA	
Brazil	SARS-CoV-2 (COVID19) IgM ELISA	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	SARS-CoV-2 (COVID19) IgA ELISA	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	SARS-CoV-2 (COVID-19) IgG ELISA	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Quick PROFILE COVID19 IgG/IgM Test Card	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Familia Teste de antocorpo SARS-CoV-2 (immunocromatografia - ouro colodial)	Arquimed Distribuidora de Produtos Medicos - Eireli - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	SARS-CoV-2 S gene for BD Max	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	BD SARS-CoV-2 Reagents for BD MAX System	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Teste Rápido OnSite™ COVID-19 IgG/IgM	BIO ADVANCE DIAGNOSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus

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Brazil	Kit de Detecção por PCR em Tempo Real VIASURE SARS-CoV-2	BIOMÉDICA EQUIPAMENTOS E SUPRIMENTOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	SARS-COV-2 R-GENE	BIOMERIEUX BRASIL INDUSTRIA E COMERCIO DE PRODUTOS LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	DIAGNOSTIC KIT FOR NOVEL-CORONAVIRUS (2019-NCOV) RNA (PCR-FLUORESCENT PROBE ASSAY)	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	NEW CORONAVIRUS IGG/IGM RAPID TEST KIT (COVID-19 IgG/ IgM)- CASSETE	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Diagnostic Kit for Novel-Coronavirus(2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus

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Brazil	Diagnostic Kit for Novel Coronavirus(2019nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS LTDA - EP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	NEW CORONAVIRUS IGG/IGM RAPID TEST KIT (COVID-19 IgG/ IgM)	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	AFIAS COVID-19 Ab	Biosys LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	ichroma COVID-19 Ab	BIOSYS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	COVID-19 Real-Time PCR Kit	BRAZIL 3 BUSINESS PARTICIPAÇÕES LTDA me	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	Celer Sansure Kit de Detecção por PCR em Tempo Real para SARSCoV-2	Celer biotecnologia	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus
Brazil	One Step COVID-2019 Test	CELER BIOTECNOLOGIA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADrus

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Brazil	Cellex qSARSCoV-2 IgG/IgM Cassette Rapid Test	CELLEX, INC. – UNITED STATES OF AMERICA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM	CEPALAB LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Xpret Xpress SARS-CoV-2	Cepheid Brasil Omportação Exportação e Comércio de Productos de Diagnosticos Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	DPP® COVID-19 IgM/IgG System	CHEMBIO DIAGNOSTICS BRAZIL LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Asan Easy Teste Covid19 IgG/IgM	COMERCIAL JEFS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit PCR Fluorescence Probing	CPMH – Comércio e Indústria de Produtos Médico- Hospitalares e Odontológicos LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM test	DFL INDUSTRIA E COMERCIO	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	GenePro COVID-19 Detection Test	DFL INDÚSTRIA E COMÉRCIO S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	COVID-19 IgG/IgM Rapid Test	DIAGNÓSTICA INDÚSTRIA E COMÉRCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CORONAVÍRUS RAPID TEST	DIAGNÓSTICA INDÚSTRIA E COMÉRCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	LIAISON® SARS-CoV-2 S1/S2 IgG	DIASORIN LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold Immunochromatography)	DR IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CORONAVÍRUS IgG/IgM (COVID-19)	EBRAM PRODUTOS LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS CoV-2 ECO Detect	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 Ag ECO Teste	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM ECO Teste	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ECO F COVID-19 Ag	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Combo ECO Teste	Eco Diagnóstica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	EURORealTime SARSCoV-2	Euroimmun BRASIL MEDICINA DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Anti-SARS-CoV-2 ELISA IgA	EUROIMMUN BRASIL MEDICINA DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Anti-SARS-CoV-2 IgG ELISA	EUROIMMUN BRASIL MEDICINA DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido COVID-19 IgG / IgM Bahiafarma	FUNDAÇÃO BAIANA DE PESQ. CIENTIFICA E DESENV. TECNOLÓGICO, FORNECIMENTO E DISTRIBUIÇÃO DE MEDICAMENTOS- BAHIAFARMA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit MOLECULAR SARS-CoV2 (E/P1) - Bio-Manguinhos	FUNDAÇÃO OSWALDO CRUZ	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	TR DPP® COVID-19 IGM/IGG - Bio- Manguinhos	FUNDAÇÃO OSWALDO CRUZ	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Kit	Future Medical Eireli EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM	GOLD ANALISA DIAGNÓSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Veri-Q PCR 316 Coronavirus disease 2019(COVID-19) -	GOYAZES BIOTECNOLOGIA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	Detection Kit nCoV-QS		
Brazil	SARS-CoV-2 Antibody Test – Lepu Technology	idoramed importação distribuição e comércio de materiais médicos hospitalares eireli epp	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 IgM/IgG	IN VITRO DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM	IN VITRO DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	n-COVID-19 IgM/IgG Ouro Coloidal	IN VITRO DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	GeneFinderTM COVID19 PLUS RealAmp Kit	INSTITUTO BUTANTAN	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	KOVID ab (COVID-19 IgG/IgM)	KOVALENT DO BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	DETECT SARSCoV-2 RT-PCR	LABTEST DIAGNOSTICA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Anti COVID-19 IgG/IgM Rapid Test	LABTEST DIAGNOSTICA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	LANG SARS-CoV-2 Antibody Test	LANG E FILHOS MATERIAL HOSPITALAR LTDA ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	TESTE RAPIDO CORONAVÍRUS REALY TECH	LEVEL IMPORTAÇÃO, EXPORTAÇÃO E COMÉRCIO S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	TaqPath COVID-19 CE-IVD-RT PCR Kit	LIFE TECHNOLOGIES BRASIL COMERCIO E INDUSTRIA DE PRODUCTOS PARA BIOTECNOLOGIA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	LUMIRATEK COVID-19 (IgG/IgM)	LUMIRADIX HEALTHCARE LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIOSYNEX COVID-19 BSS	MANDALA BRASIL IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTO MÉDICO HOSPITALAR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Tira de Teste de Anticorpo contra SARSCoV-2 (Método de Ouro Coloidal)	MANTARAY IMPORTAÇÃO E COMÉRCIO DE PRODUTOS MÉDICOS E CIRÚRGICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ALLSERUM EIA COVID 19 IGM	MBIOLOG DIAGNOSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ALLSERUM EIA COVID 19 IGG	MBIOLOG DIAGNOSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	MedTeste Coronavírus (COVID-19) IgG/IgM (TESTE RAPIDO)	MEDLEVENSOHN COMÉRCIO E REPRESENTAÇÕES DE PRODUTOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	COVID-19 IgG/IgM Test Cassette	MEDSTAR IMPORTAÇÃO E EXPORTAÇÃO EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	KIT DE TESTE RAPIDO PARA COVID-19	MEDTEC SUPPLIES, INDUSTRIA, IMPORTACAO, EXPORTACAO, DISTRIBUICAO E COMERCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família KIT XGEN MASTER COVID-19 – Kit Master para Detecção do Coronavírus SARS-CoV-2	MOBIUS LIFE SCIENCE INDÚSTRIA E COMERCIO DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Cellex qSARSCoV-2 IgG/IgM Cassette Rapid Test	NL COMÉRCIO EXTERIOR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NL qSARSCoV-2 IgG/IgM Cassette Rapid Test	NL COMÉRCIO EXTERIOR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NL qSARS-CoV-2 IgG/IgM Cassette Rapid Test	NL COMÉRCIO EXTERIOR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido COVID-19 I15 minutos Nutriex	NUTRIEX IMPORTACAO E EXPORTACAO DE PRODUTOS NUTRICIONAIS E FARMOQUIMICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 TESTE DE ANTICORPO (IMUNOCROMATOGR	NUTRIMEX MEDICAL IMPORTAÇÃO E DISTRIBUIÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SAR S-CoV-2) (Lateral Flow)	OLTRAMED COMERCIO DE PRODUTOS MEDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste para anticorpos de SARS-CoV-2 (imunocromatografia com ouro coloidal)	OLTRAMED COMERCIO DE PRODUTOS MEDICOS LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Diagnostic kit for antibody IgM/IgG of novel coronavirus COVID-19	OPTME IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS LTDA – ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Alfa Test	ORBITAE DIAGNOSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Assure Test	ORBITAE DIAGNOSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família COVID-19 IgG/IgM Teste Rápido (Sangue total/ Soro/Plasma)	QR Consulting, Importação e Distribuição de Produtos Médicos Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Teste Rápido em Cassete 2019-nCoV IgG/IgM (sangue total/soro/plasma)	QR Consulting, Importação e Distribuição de Produtos Médicos Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Teste Rápido em Tira	QR Consulting, Importação e	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		Distribuição de Produtos Médicos Ltda	
Brazil	Leccurate - SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	QUANTUM - IMPORTACAO E DISTRIBUICAO DE PRODUTOS MEDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Familia Bio GENE COVID-19 PCR	QUIBASA QUIMICA BASICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM BIO	QUIBASA QUIMICA BASICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	RENOVA MEDICAL INDÚSTRIA E COMÉRCIO DE PRODUTOS MÉDICOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Imunotest COVID-19	RENYLAB QUÍMICA E FARMACÊUTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM	RENYLAB QUÍMICA E FARMACÊUTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Elecsys Anti-SARS-CoV2	ROCHE DIAGNÓSTICA BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família cobas® SARS-CoV-2	Roche Molecular System, Inc	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Casete Diagnóstico Teste de Anticorpos para SARS-CoV-2	SAO JUDAS MATERIAIS MEDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	SARS-CoV-2 IgG & IgM Ab Diagnostic Test kit (Colloidal Gold)	TECMEDIC COMÉRCIO DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM KIT DE TESTE RÁPIDO	Tekmarket Industria, comércio e serviços limitada	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Device (WB/S/P)	Una Medic Importacao e Exportação	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Device (WB/S/P)	Una Medic Importacao e Exportação	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Device (WB/S/P)	UNA MEDIC IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	GeneFinder COVID-19 Plus	UNA MEDIC IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	QuickProfil COVID-19 IgG/IgM Combo Test Card	VELOZ IMPORTADORA E DISTRIBUIDORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	QuickProfile COVID-19 IgG/IgM Combo Test Card	VeloZ Importadora e Distribuidora Ltda epp	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 VIRCLIA IgG MONOTEST	VIRION DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 VIRCLIA IgM/IgA MONOTEST	VIRION DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	SARS-COV-2 RT- PCR KIT	VIRION DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 ELISA IgG	VIRION DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 ELISA IgM+IgA	VIRION DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	RealStar® SARS-CoV-2 RT-PCR Kit 1.0	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	MAGLUMI IgG de 2019-nCoV (CLIA)	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	MAGLUMI IgM de 2019-nCoV (CLIA)	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	AllplexTM 2019-nCoV Assay	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		PRODUTOS MÉDICOS LTDA	
Brazil	Smart Test Covid-19 Vyttra	VYTTRA DIAGNOSTICOS IMPORTACAO E EXPORTACAO S.A.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Asan Easy Test Covid19 IgG_IgM	W N COMÉRCIO IMPORTAÇÃO E REPRESENTAÇÕES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Imuno-Rápido COVID19 IgG/IgM	WAMA PRODUTOS PARA LABORATORIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	REALY TECH TEST 2019-n COV IgG/Ig	ADVANCED MED IMPORTADORA E EXPORTADORA DE PRODUTOS FARMACÊUTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIOCREDIT COVID-19 AG	CLAC IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Anti-SARS-CoV-2-NCP ELISA (IgG)	Euroimmun Brasil Medica Diagnostica LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV Ab Test (Colloidal Gold)	Future Medical Eireli EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavirus (SARS-CoV-2) Antibody (IgM/IgG) Test	GoldMed Importação de Produtos Hospitalares	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	kit diagnóstico de anticorpos IgM/IgG	MEDICAL HEALTH COMÉRCIO, SERVIÇOS E IMPORTAÇÃO EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	para coronavírus (SARS-CoV-2)		
Brazil	kit diagnóstico de anticorpos IgM/IgG para coronavírus	NEOBRAx LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	"Teste para anticorpos de SARS-CoV-2 (imunocromatografia com ouro coloidal)"	"PASSROD IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS PARA SAÚDE LTDA – ME"	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de anticorpo SARS-CoV-2 (imunocromatografia em ouro coloidal)	RADIOMED COMERCIO E IMPORTACAO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de anticorpo SARS-CoV-2 (imunocromatografia em ouro coloidal)	SINERGIA MÉDICA COMÉRCIO DE ARTIGOS MÉDICOS E ORTOPÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019 - nCoV Ab Test (colloidal Gold)	sm empreendimentos farmacêuticos Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Cassete de Teste Rápido (Total Sangue/Soro/Plasma)	UBUNTU MED IMPORTADORA E DISTRIBUIDORA DE PRODUTOS PARA SAUDE LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Test IgM/IgG SARS-CO-2	YIN'S BRASIL COMERCIO INTERNACIONAL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Alinity i SARSCoV-2 IgG	ABBOTT LABORATÓRIOS DO BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	QuickProfile 2019-nCoV IgG/IgM Test Card	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV Ab Test (Colloidal Gold)	BONELINK COMERCIO, SERVICOS, IMPORTACAO E EXPORTACAO DE PRODUTOS MEDICOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste Rápido COVID-19 IgG/IgM Assure Tech	MS BASTOS COMERCIO E REPRESENTAÇÕES LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavírus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)	OSTHEON COMÉRCIO IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	QuickProfile® 2019-nCoV IgG/IgM Combo Test Card	VELOZ IMPORTADORA E DISTRIBUIDORA LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novo kit de teste de anticorpos IgM / IgG para coronavírus (2019-nCoV) (ouro coloidal)	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit SARS-CoV-2 Antibody Test	AQUA BLUE COMÉRCIO IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste Rápido COVID-19 IgG/IgM	CONSUMERSLAB PRODUTOS PARA LABORATÓRIOS E HOSPITAIS LTDA. EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	"2019-nCoV Antibody Diagnostic Kit"	CPMH - Comércio e Indústria de Produtos Médico-Hospitalares e Odontológicos LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	"Artron COVID-19 IgM/IgG test"	DR IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ECO F COVID-19 IgG/IgM	Eco Diagnóstica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ErbaLisa® COVID-19 IgM	Erba Diagnostics Brazil, Producao e Distribuicao de Produtos Medicos Eireli	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19-CHECK -1	FASTTEST DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de anticorpo SARS-CoV-2 (imunocromatografia em ouro coloidal)	FOCCUS MEDICAL EQUIPAMENTOS MEDICOS EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	EGENS COVID-19 IgG/IgM Rapid Test Kit	GLOBOMEDICAL PRODUTOS MEDICOS EIRELI - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit	IMEX MEDICAL COMÉRCIO E LOCAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 IgG/IgM	JOTAMED COMÉRCIO E REPRESENTAÇÃO DE PRODUTOS	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		MÉDICOHOSPITALARES LTDA.	
Brazil	Teste Rápido para COVID-19 IgG/IgM	LIFETRON BIOTECNOLOGIA LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Instant-View® plus COVID-19 IgG/IgM Antibody Test	NL COMÉRCIO EXTERIOR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NL COVID-19 IgG/IgM Antibody Test	NL COMÉRCIO EXTERIOR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	VITROS Immunodiagnostic Products Anti-SARSCoV-2 Total Reagent Pack, Calibrator, Control	ORTHO CLINICAL DIAGNÓSTICS DO	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-COV-2 ANTIBODY TEST (Colloidal gold immunochromatography) RBT Group	rbtg brasil equipamentos médicos hospitalares ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	GOLD ELISA COVID-19 IgG+IgM	"REM INDÚSTRIA E COMÉRCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)	SAUDE MAIS IND EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FTD SARS-CoV-2	SIEMENS HEALTHCARE DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Família Atellica IM SARS-CoV-2 Total (COV2T)	SIEMENS HEALTHCARE DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Allplex™ SARS-CoV-2 Assay	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgM MAX ELISA	ADVAGEN BIOTECH LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG MAX ELISA	ADVAGEN BIOTECH LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgA MAX ELISA	ADVAGEN BIOTECH LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	RADI COVID-19 KIT DETECÇÃO	ADVANCED MED IMPORTADORA E EXPORTADORA DE PRODUTOS FARMACÊUTICOS LTDA ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-COV-2 ANTIBODY TEST	BIOASSIST COMERCIAL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de teste de anticorpos SARS-CoV-2	BIOSENSOR INDÚSTRIA E COMÉRCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Cassette	COVID-19 IgG/IgM Rapid Test Cassette	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	SARS-CoV-2 Antibody Test	CICLO MED DO BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CICLO MED DO BRASIL LTDA	CONTOURLINE EQUIPAMENTOS MÉDICOS E ESTÉTICOS LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Device	EQUILIBRIO COMÉRCIO DE PRODUTOS FARMACÊUTICOS EIRELI EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ErbaLisa® COVID-19 IgG	Erba Diagnostics Brazil, Producao e Distribuicao de Produtos Medicos Eireli	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)	med 7 produtos hospitalares Ltda epp	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FOSUN 2019-nCoV qPCR	MS BASTOS COMERCIO E REPRESENTAÇÕES LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV Kit de Detecção IgG/IgM (Ouro Coloidal)	OPTME IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS LTDA – ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG/IgM Detection Kit	ORTOMEDIC DISTRIBUIDORA DE PRODUTOS MEDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIOLISA COVID-19 IgG	QUIBASA QUIMICA BASICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	BIOLISA COVID-19 IgM	QUIBASA QUIMICA BASICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test	ROFEMAX IMPORTADORA DE EMBALAGENS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG CONFIRMAÇÃO	SERION BRASIL IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTOS DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG	SERION BRASIL IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTOS DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgM	SERION BRASIL IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTOS DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 IgM/IgG Antibody Assay Kit	SILIMED - INDÚSTRIA DE IMPLANTES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	LECCURATE - TESTE DE ANTICORPOS PARA SARS-COV-2 (IMUNOCROMATOGR A FIA COM OURO COLOIDAL)	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FOSUN 2019-nCoV qPCR	YIN'S BRASIL COMERCIO INTERNACIONAL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Kit de teste de anticorpos IgM / IgG para novo coronavírus (2019-nCoV) (ouro coloidal)	ADAPT PRODUTOS OFTALMOLÓGICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG/IgM Detection Kit	ALC ALERGIA CLÍNICA LABORATORIAL E COMÉRCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste One Step para Anticorpos IgM / IgG do Novo Coronavírus (2019-nCoV) (Ouro Coloidal)	BIOMÉDICA EQUIPAMENTOS E SUPRIMENTOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Test Antibody (colloidal Gold immunochromatography)	BIOTECNICA INDUSTRIA E COMERCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (Lateral Flow Method)	CEMED COMÉRCIO IMPORTAÇÃO EXPORTAÇÃO E DISTRIBUIÇÃO LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 PCR	CEPALABLABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de Covid 19 Leccurate (imunocromatografia ouro coloidal)	CIRURGICA FERNANDES - COMERCIO DE MATERIAIS CIRURGICOS E HOSPITALARES - SOCIEDADE LIMITADA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de anticorpo SARS-CoV-2	CKTRADE IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	(imunocromatografia em ouro coloidal)		
Brazil	SARS-CoV-2 Antibody Test	CRITICARE COMÉRCIO DE PRODUTOS CIRÚRGICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste rápido Anti-SARS-CoV-2	Diagmaster Científica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	DORTE DISTRIBUIDORA, IMPORTADORA E EXPORTADORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	DR IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CORONAVÍRUS IgG/IgM (COVID-19)	EBRAM PRODUTOS LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste rápido anticorpo SARS-CoV-2	GANESH LOGISTICA E DISTRIBUICAO EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Artron COVID-19 IgM/IgG Antibody test	Key Trade Importadora e Exportadora Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Dispositivo para Teste Rápido COVID-19 IgG /IgM	MF MEDICAL - EIRELI - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Rapid 2019-nCoV IgG/IgM Combo Test Card	Molecular Biotecnologia e Representação LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	HC405	MULTILASER INDUSTRIAL S.A.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit	PLENO DISTRIBUIDORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CONTROLE INTERNO COVID-19 (SORO) IgG e IgM	programa nacional de controle de qualidade ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	PreciControl Anti-SARS-CoV-2	ROCHE DIAGNÓSTICA BRASIL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	SETTY ASSESSORIA E CONSULTORIA EM ASSUNTOS REGULATORIOS COM DE PROD MEDICO HOSPITALARES EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família ADVIA Centaur SARS-CoV-2 Total (COV2T)	SIEMENS HEALTHCARE DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ANTI-COVID19 VIRUS IGM-IGG TEST KIT	SS WHITE ARTIGOS DENTARIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de anticorpo SARS-CoV-2 (imunocromatografia em ouro coloidal)	Unigloves Brasil Importadora LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	UNIK COMERCIAL IMPORTADORA E EXPORTADORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	COVID-19 (SARS-COV-2)	3W DO BRASIL IMPORTACAO E EXPORTACAO S.A.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de teste de anticorpos IgM / IgG para novo coronavírus (2019-nCoV) (ouro coloidal)	ADAPT PRODUTOS OFTALMOLÓGICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família de Reagente, Calibrador e Controle Access SARS-Cov-2 IgG	BECKMAN COULTER DO BRASIL COMÉRCIO E IMPORTAÇÃO DE PRODUTOS DE LABORATÓRIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	BIOGEN COMERCIAL E DISTRIBUIDORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família careGENE COVID-19 RT-PCR	BLAU FARMACÊUTICA S.A.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CELER HIGHTOP IGG IGM COVID	CELER BIOTECNOLOGIA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV2(COVID-19)IgG/IgM	CLAC IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste rápido IgG e IgM para SARS-CoV-2 (por imunocromatografia em ouro coloidal)	DBI - COMÉRCIO E IMPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Teste de anticorpos (Ouro Coloidal) para COVID-19	Domo Salute Consultoria Regulatória Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	StrongStep® SARS-CoV-2 IgM/IgG Test	DR IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)	ENSOFILL PRODUTOS ESTETICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	HIGHTOP SARS-CoV-2 IgM/IgG rapid test	FARMA VISION IMPORTAÇÃO E EXPORTAÇÃO DE MEDICAMENTOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 IgG/IgM	GOLD ANALISA DIAGNÓSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	GoldMed Importação de Produtos Hospitalares Ltda ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Dispositivo de teste rápido 2019-nCoV IgG/IgM	IMEX MEDICAL COMÉRCIO E LOCAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Tira de Teste de Anticorpo SARS-CoV-2 (Método de Ouro Coloidal)	INTERVALUE COMERCIAL IMPORTADORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Realy Teste Rápido 2019-nCoV Coronavirus	Key Trade Importadora e Exportadora Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	TESTE DE ANTICORPOS	MF MEDICAL - EIRELI - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	(IGM/IGG) PARA NOVO CORONAVÍRUS (SARSCOV-2)		
Brazil	Kit de teste rápido novo Coronavirus (2019-nCoV) IgM/IgG	MS BASTOS COMERCIO E REPRESENTAÇÕES LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	LEPU SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	MULT DIAGNOSTICA LTDA-ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography) - Leccurate	NORDESTE MEDICAL, REPRESENTACAO, IMPORTACAO E EXPORTACAO DE PRODUTOS HOSPITALARES LTDA EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Detecção Rápida SARS-CoV-2 IgG/IgM Parts Import	PARTS IMPORT COMÉRCIO DE IMPORTAÇÃO E EXPORTAÇÃO LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	PROLIFE LEGALIZACAO, IMPORTACAO E DISTRIBUICAO DE PRODUTOS LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit IgG / IgM (ouro coloidal) para o Covid-19	PV COMERCIO ATACADISTA DE MAQUINAS E EQUIPAMENTOS EIRELI	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Kit	Radac Importadora e Distribuidora Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	CASSETE DE TESTE RÁPIDO IGG/IGM COVID-19 (WB/S/P)	Radac Importadora e Distribuidora Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de anticorpos para SARS-CoV-2 (por imunocromatografia em ouro coloidal)	SILTACE COMERCIO DE PRODUTOS HOSPITALARES LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019 n-CONV IgG/IgM Detection kit	SILTACE COMERCIO DE PRODUTOS HOSPITALARES LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Dispositivo de teste rápido 2019-nCoV IgG/IgM	SOUPELLI INDUSTRIA E COMERCIO EIRELI - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)	UP MED DISTRIBUIDORA E IMPORTADORA DE MATERIAIS HOSPITALARES LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de Anticorpos(IgM/igG) Para Coronavírus(COVID-19)	YIN'S BRASIL COMERCIO INTERNACIONAL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido Richards IgG/IgM - SARS-CoV-2	ALPHALIFE MATERIAIS MÉDICO HOSPITALARES LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 (SARS-CoV-2)	AMARILES COMERCIAL IMPORTADORA EXPORTADORA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Quicknostics COVID-19 RT PCR	ARGOSLAB DISTRIBUIDORA DE	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		PRODUTOS PARA LABORATÓRIOS LTDA	
Brazil	GSD NovaPrime SARSCoV-2 (COVID-19) RTPCR	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test – Ergon Sutramed	ASSUT EUROPE LATINO AMERICA IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de Anticorpo IgG/IgM do Novo Coronavirus (nCoV-2019 (Ouro Coloidal)	ASSUT EUROPE LATINO AMERICA IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido IgM/IgG para SARS-CoV-2	ÁVITA CARE IMPORTAÇÃO E DISTRIBUIÇÃO DE PRODUTOS LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavirus (2019-nCoV) IgM/IgG	BIOGEN COMERCIAL E DISTRIBUIDORA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	CHAZAK VE EMATZ COMERCIAL IMPORTADORAS E EXPORTADORAS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG / IgM Detection Kit - Vazyme	CPMH - Comércio e Indústria de Produtos Médico-Hospitalares e Odontológicos LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test	DMR INDÚSTRIA E COMÉRCIO DE MATERIAIS ODONTOLÓGICOS LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Covid-19 Antibody Rapid Test	EQUILIBRIO COMÉRCIO DE PRODUTOS FARMACÊUTICOS EIRELI EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Kit	ESALAB IMPORTAÇÃO EXPORTAÇÃO E COMÉRCIO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ScheBooe SARS-CoV-2 Quick	FARMA VISION IMPORTAÇÃO E EXPORTAÇÃO DE MEDICAMENTOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	TR COVID-19 IGM/IGG - Bio-Manguinhos	FUNDAÇÃO OSWALDO CRUZ	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	KIT DE TESTE COVID-19	LMG LASERS - COMERCIO, IMPORTACAO E EXPORTACAO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Covid-19 IgM/IgG (ouro coloidal)	Massy do Brasil Comercio Exterior LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ALLSERUM EIA Covid-19	MBIOLOG DIAGNOSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste rápido COVID-19 IgG/IgM Nutriex	NUTRIEX IMPORTACAO E EXPORTACAO DE PRODUTOS NUTRICIONAIS E FARMOQUIMICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	KIT DE DETECÇÃO DE IGM / IGG PARA O NOVO CORONAVÍRUS	PENSABIO INSTRUMENTOS DE BIOTECNOLOGIA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	(COVID-19) (À BASE DE OURO COLOIDAL)		
Brazil	COVID-19 IgG/IgM	RETTERMED COMÉRCIO DE MATERIAL MÉDICO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Dimension SARS CoV 2 Anticorpo Total (CV2T)	SIEMENS HEALTHCARE DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste Rápido COVID-19 IgG/IgM	TKL IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS MÉDICOS E HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste COVID-19 IgG/IgM TOCARE	TOCARE INDUSTRIA E COMERCIO DE PRODUTOS MEDICOS	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	QuickProfile COVID-19 Antigen Test	ARGOSLAB DISTRIBUIDORA DE PRODUTOS PARA LABORATÓRIOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	VIDAS® SARS-COV-2 IgG (9COG)	BIOMERIEUX BRASIL INDUSTRIA E COMERCIO DE PRODUTOS LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	IgM (9COM)	BIOMERIEUX BRASIL INDUSTRIA E COMERCIO DE PRODUTOS LABORATORIAIS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	iFlash-SARS-CoV-2 IgG	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS LTDA - EPP	
Brazil	iFlash-SARS-CoV-2 IgM	BIOMOLECULAR TECHNOLOGY COMÉRCIO, IMPORTAÇÃO, EXPORTAÇÃO E DISTRIBUIÇÃO DE MATERIAIS MÉDICOS E LABORATORIAIS LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Diagnóstico para SARS-COV-2 IgM/IgG Anticorpos – Ouro Coloidal	BUZZY COMERCIAL IMPORTAÇÃO E EXPORTAÇÃO LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido Liming Bio StrongStep® SARSCoV-2 IgM/IgG	CLAC IMPORTAÇÃO E EXPORTAÇÃO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 TEST BIOCON	DIAGNÓSTICA INDÚSTRIA E COMÉRCIO LTDA - ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	STANDARD Q COVID-19 IgM/IgG Combo Test	Eco Diagnóstica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de diagnóstico para SARS-CoV-2 anticorpo IgM / IgG	EINCO BIOMATERIAL LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Coronavirus disease(COVID-19) Antibody Test (Colloidal Gold)	EMERGO BRAZIL IMPORT IMPORTACAO E DISTRIBUICAO DE	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		PRODUTOS MEDICOS HOSPITALARES LTDA	
Brazil	2019-nCoV RT-qPCR Detection Kit	EMERGO BRAZIL IMPORT IMPORTACAO E DISTRIBUICAO DE PRODUTOS MEDICOS HOSPITALARES LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido COVID-19	ENDO-MASTER COMÉRCIO DE EQUIPAMENTOS	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Lab-On-Time COVID-19 Rapid Diagnostic Kit	FARMA VISION IMPORTAÇÃO E EXPORTAÇÃO DE MEDICAMENTOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de Diagnóstico de Anticorpos IgM/ IgG para SARS-CoV-2 (Ouro Coloidal)	FUJICOM COMERCIO DE MATERIAIS HOSPITALARES E IMPORTACAO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de Diagnóstico para SARS-CoV-2 Ácido Nucleico (PCR em tempo real)	FUJICOM COMERCIO DE MATERIAIS HOSPITALARES E IMPORTACAO LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV Kit de detecção de IgG / IgM (baseado em ouro coloidal)	J T Freire me	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BioMar – Coronavírus (COVID-19) IgG/IgM II	RIOMAR TRADING LTDA-ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Biomar Teste Coronavírus (COVID-	RIOMAR TRADING LTDA-ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	19) IgM (Teste Rápido)		
Brazil	Família Atellica IM SARS-CoV-2 IgG (COV2G)	SIEMENS HEALTHCARE DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família ADVIA Centaur SARS-CoV-2 IgG (COV2G)	SIEMENS HEALTHCARE DIAGNÓSTICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	KIT TESTE RAPIDO SARS-CoV-2 IgG/IgM (MÉTODO OURO COLLOIDAL)	Unigloves Brasil Importadora LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família AFIAS COVID-19 Ag	BIOSYS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ichroma COVID-19 Ag	BIOSYS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	OL COVID-19 IgM/IgG	CHEMBIO DIAGNOSTICS BRAZIL LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM KIT DE TESTE RÁPIDO	Domo Salute Consultoria Regulatória Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NOVEL CORONAVIRUS (2019-nCoV) IgG/IgM	Test Kit DUDER PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	kit de teste de anticorpos IgG / IgM para coronavírus (2019-nCoV) (ouro coloidal)	F2R TRADE IMPORT EXPORT LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	LEPU MIVIDA DISTRIBUIDORA DE PRODUTOS MÉDICOS E INSTRUMENTOS LTDAME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit Diagnóstico para anticorpo IgM/IgG do novo Coronavírus COVID-19	SILTACE COMERCIO DE PRODUTOS HOSPITALARES LTDA - EPP	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CELER FINECARE SARS-CoV-2 IgM/IgG Test	CELER BIOTECNOLOGIA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	TESTE RÁPIDO COVID-19 IgM / IgG GOLD	DPM COMÉRCIO E REPRESENTAÇÕES LTDA ME	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	2019-nCoV IgG/IgM Rapid Test Device	LOGIGO HEALTH & HEALTH, TECNOLOGIA AUTOMOTIVA COMERCIO, IMP FAB PROD AREA MEDICO - HOSPITALAR LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste de Anticorpos do COVID-19 IgM/IgG (Ouro Coloidal)	VR MEDICAL IMPORTADORA E DISTRIBUIDORA DE PRODUTOS MÉDICOS LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	KIT DE DIAGNÓSTICO PARA SARS-COV-2 ÁCIDO NUCLEICO (PCR EM TEMPO REAL)	SHANGHAI KEHUA BIO-ENGINEERING CO LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	NADAL® COVID-19 IgG/IgM (Ref. 243003N-25)	NAL VON MINDEN	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FOSUN 2019-nCoV qPCR	SHANGHAI FOSUN LONG MARCH MEDICAL SCIENCE CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 Ag	QINGDAO HIGHTOP BIOTECH CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	OL COVID-19 Ag	CHEMBIO DIAGNOSTICS BRAZIL LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Standard E Covid 19 Total Ab ELISA	SD BIOSENSOR, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Cassette	ZHEJIANG ORIENT GENE BIOTECH CO, LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	HANGZHOU CLONGENE BIOTECH CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography) Teste de Anticorpos SARS-CoV-2 (imunocromatografia com ouro coloidal)	BEIJING LEPU MEDICAL TECHNOLOGY CO.,LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Rapid Response™ COVID 19 IgG / IgM	BTNX, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	Test Cassette (Sangue total / soro / plasma)		
Brazil	Família SARS-CoV-2 IgM	ABBOTT IRELAND DIAGNOSTICS DIVISION	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Alinity i SARS-CoV-2 IgM	ABBOTT IRELAND DIAGNOSTICS DIVISION	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	AccuraDTect SARS-CoV-2 RT-qPCR Kit	GENOMICTREE, INC	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Ensaio Quantitativo de Antígeno SARS-CoV-2 (Imunoensaio ligado à enzima)	BIOHIT HEALTHCARE (HEFEI) CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BEIER IGM/IGG RAPID TEST CASSETTE (WB/S/P)	BEIJING BEIER BIOENGINEERING CO LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	VERI Q COVID-19 Kit de Detecção Multiplex nCoV-OM/nCoV-QM	MICROBIOMED CO.,LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Spring teste rápido IgG/IgM COVID-19	SPRING HEALTHCARE SERVICES AG	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Dimension SARS-CoV-2 IgG (CV2G)	SIEMENS HEALTHCARE DIAGNOSTICS, INC. –	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Tira de teste de anticorpo do SARS-CoV-2 IgG / IgM	REDPHARM (CHANGCHUN)	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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	(Método de ouro coloidal)	BIOTECHNOLOGYCO., LTD	
Brazil	Teste Rápido de Anticorpos para Doença de Novo Coronavírus (COVID-19) IgM/IgG (Ouro Coloidal)	BEIJING HOTGEN BIOTECH CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	VERI Q COVID-19 Kit de Detecção Multiplex nCoV-OM/nCoV-QM	MICROBIOMED CO.,LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Anti SARS-CoV-2 IgM/IgG Rapid Test	LABTEST DIAGNOSTICA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CORIS Bioconcept® COVID-19 Ag Respi-Strip	Nanosens Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Instant-View® Plus COVID-19 Antigen Test	ALFA SCIENTIFIC DESIGNS, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIOCLIN FAST COVID-19 IgG/IgM	QUIBASA QUÍMICA BÁSICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 IgM/IgG Detection Kit (Colloidal Gold-Based)	IMMUNODIAGNOSTICS LIMITED	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SAFETEST COVID-19TM IgG/IgM- Kit ELISA	Vida Biotecnologia Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	COVID-19 AG RAPID TEST	HUMASIS CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Covid-19 Ag C ECO Teste	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FREND COVID-19 IgG/IgM DUO	NANOENTEK INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste Covid 19(SARS-CoV-2) Anticorpo IgG/IgM Ouro Colidal	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família SARS-CoV-2 IgG (CLIA)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Kit SARS-CoV-2 IgM (CLIA)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 RT-qPCR Reagent Kit 3501-0010 / 3502-0010	WALLAC OY	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG Teste Rápido (Sangue Total / Soro / Plasma)	ACRO BIOTECH INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de diagnóstico para Anticorpo IgM/IgG de Novo Coronavirus COVID-19	SHANGHAI LIANGRUN BIOMEDICINE TECHNOLOGY CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 Ag Rápido	Vida Biotecnologia Ltda -	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	COVID-19 AG RAPID TEST	HUMASIS CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Covid-19 Ag C ECO Teste	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FREND COVID-19 IgG/IgM DUO	NANOENTEK INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste Covid 19(SARS-CoV-2) Anticorpo IgG/IgM Ouro Colidal	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família SARS-CoV-2 IgG (CLIA)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Kit SARS-CoV-2 IgM (CLIA)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 RT-qPCR Reagent Kit 3501-0010 / 3502-0010	WALLAC OY	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 IgG Teste Rápido (Sangue Total / Soro / Plasma)	ACRO BIOTECH INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de diagnóstico para Anticorpo IgM/IgG de Novo Coronavirus COVID-19	SHANGHAI LIANGRUN BIOMEDICINE TECHNOLOGY CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 Ag Rápido	Vida Biotecnologia Ltda -	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Kit GeneFinder COVID- 19 Plus RealAmp	OSANG HEALTHCARE CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCRFluorescence Probing)	DA AN GENE CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	1copy™ COVID-19 qPCR Multi Kit	1DROP INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Tell Me Fast Teste para Detecção de Anticorpos IgG/IgM do Novo Coronavírus (COVID-19)	BIOCAN DIAGNOSTICS	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Rapid Antibody Test	SD BIOSENSOR, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família ID NOW COVID-19	ABBOTT DIAGNOSTICS	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste de Anticorpos SARS-CoV-2 IgM/IgG	CHANGSHA SINOCARE INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	GenBody COVID-19 AG	GENBODY INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 AG RAPID TEST	LABTEST DIAGNOSTICA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	MAGLUMI® SARS-CoV- 2 S-RBD IgG (CLIA)	SHENZHEN NEW INDUSTRIES	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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		BIOMEDICAL ENGINEERING CO., LTD	
Brazil	COVID-19 IgG pS MAX	ADVAGEN BIOTECH	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Panbio™ COVID-19 Ag	ALERE S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família de Reagente, Calibrador e Controle Access SARS-Cov-2 IgM	BECKMAN COULTER, INC	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Humasis COVID-19 Ag	HUMASIS CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Covid Ag Oral ECO Detect	Eco Diagnostica Ltda	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NeoPlex COVID-19 Detection Kit	GENEMATRIX, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	COVID-19 Coronavirus Real Time PCR Kit	JIANGSU BIOPERFECTUS TECHNOLOGIES CO.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 Ag InviTest	IN VITRO DIAGNOSTICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SARS-CoV-2 IgM/IgG Antibody Assay Kit (Colloidal Gold Method)	ZYBIO INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	GSP/Delfia Anti-SARSCoV-2 IgG kit PN 3503-10	WALLAC OY	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	SARS-CoV-2 Rapid Antigen Test	SD BIOSENSOR, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NowCheck COVID-19	BIONOTE, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Rapid Response™ COVID-19 Antígeno Rapid Test Device	BTNX, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	PANBIO SARS-CoV-2 IgG ELISA	AXIS SHIELD DIAGNOSTICS LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BD SARS-CoV-2 Reagents for BD MAX System IVD	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BD Veritor System For Rapid Detection of SARS-CoV-2	BECTON DICKINSON INDÚSTRIAS CIRÚRGICAS LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIO DETECHTA ELISA IgG SARS-CoV-2	BIOTECNOLOGIA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	FAMÍLIA SARS-CoV-2 ELITe MGB® Kit	ELITECH GROUP S.P.A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Human Anti-IgG/A/M SARS-CoV-2 ELISA	THE BINDING SITE GROUP LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste de Anticorpos do Novo Coronavírus 2019-nCoV (Tecnologia Imunocromatográfica de Fósforo de Conversão Ascendente)	BEIJING HOTGEN BIOTECH CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	(COVID-19) Kit de detecção rápida de anticorpos IgM/IgG (Colloidal Gold)	JIANGXI PROVINCE JINHUAN MEDICAL INSTRUMENT CO. LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Molecision™ SARSCoV-2 RT-PCR	SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	ACCEL ELISA® COVID-19	PLEXENSE INC	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido Standard Q COVID-19 IgM/IgG COMBO	SD BIOSENSOR, INC	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit Molecular SARSCoV-2 (EDx) - Bio-Manguinhos	FUNDAÇÃO OSWALDO CRUZ	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SGTi-flex COVID-19 Ag	FABRICANTE: SUGENTECH, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	AlIChék – Ensaio SARSCoV-2 RT-qPCR	HANGZHOU ALLTEST BIOTECH CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Leccurate SARS-COV-2 Teste de Antígeno	BEIJING LEPU MEDICAL TECHNOLOGY CO.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Detecção de Ácido Nucléico SARSCoV-2 (Fluorescência de RT-PCR)	BIOTECHNOLOGYCO.,LT D.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Detecção da Glicoproteína Spike	ASSUT EUROPE S.P.A –	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	BIOSURE COVID-19 ANTIBODY RAPID TEST	BIOSURE (UK) LIMITED	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	CELER HIGHTOP COVID-19 AG TEST	CELER BIOTECNOLOGIA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	DPP® SARS CoV-2 Antígeno System	CHEMBIO DIAGNOSTICS BRAZIL LTDA.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	BGI BIOTECHNOLOGY (WUHAN) CO,LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit Teste Rápido de Antígeno SARS-CoV-2	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	BGI BIOTECHNOLOGY (WUHAN) CO,LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	REAGEN TM COVID-19 IgG/IgM RAPID TEST KIT	SHENZHEN ULTRA-DIAGNOSTIC BIOTEC. CO, LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Anti SARS-CoV-2 IgM/IgG Rapid Test	LABTEST DIAGNOSTICA S/A	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido de IgG/IgM Covid-19	HANGZHOU ALLTEST BIOTECH CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Cassete de teste de IgG/IgM para COVID-19 NOVATREND	HANGZHOU ALLTEST BIOTECH CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido de Antígeno COVID-19	HANGZHOU ALLTEST BIOTECH CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Teste Rápido de Antígeno COVID-19 – ACRO	ACRO BIOTECH INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Instest – Ensaio RT-qPCR SARS-COV-2	ACRO BIOTECH INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Cassete de teste de IgG/IgM para COVID-19 APOTI	ACRO BIOTECH INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIOCLIN FAST COVID-19 Ag	QUIBASA QUÍMICA BÁSICA LTDA	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família Elecsys Anti-SARS-CoV-2 S	ROCHE DIAGNOSTICS GMBH	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	NowCheck COVID-19 IgM/IgG	BIONOTE, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	STANDARD M nCoV Real-Time Detection	SD BIOSENSOR	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Immupass VivaDiag™ SARS-CoV-2 Ag Rapid Test	VIVACHEK BIOTECH (HANGZHOU) CO., LTD.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido de IgG/IgM Covid-19	ACRO BIOTECH INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Teste Rápido do Antígeno da COVID-19 (Swab Nasofaríngeo)	HANGZHOU ALLTEST BIOTECH CO., LTD. –	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	BIOLISA COVID-19 ANTICORPO NEUTRALIZANTE	QUIBASA QUÍMICA BÁSICA LTDA –	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru

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Brazil	Kit de Teste Rápido com Antígeno de SARS- CoV-2	BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	LUMIRATEK COVID-19 Ag	HANGZHOU BIOTEST BIOTECH CO., LTD. –	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Kit de Teste Rápido com Antígeno de SARS- CoV-2	BEIJING LEPU MEDICAL TECHNOLOGY CO., LTD	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família cPass™ SARS-CoV-2 Neutralization Antibody Detection	GENSCRIPT USA INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	Família SARS-CoV-2 Antigen Rapid Test	CELLEX, INC.	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
Brazil	SOFIA® SARS ANTIGEN FIA	QUIDEL CORPORATION	For updated information on all products listed by ANVISA use this link: https://consultas.anvisa.gov.br/#/saude/q/?nomeTecnico=coronav%C3%ADru
S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™ M nCoV Real-Time Detection kit	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Real-Q 2019-nCoV Detection kit	BioSewoom, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	Q-Sens® COVID-19 Detection kit	Cancer Rop Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	U-TOPTM COVID-19 Detection Kit Plus	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	PowerChek™ SARS- CoV-2, Influenza A&B Multiplex Real-time PCR Kit	KogeneBiotech Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™ Q COVID-19 IgM/IgG Plus Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved	STANDARD™ Q COVID-19 Ag Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	AQ-TOP™ COVID-19 Rapid Detection Kit Plus	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	PowerChek™ SARS-CoV-2 Real-time PCR Kit	KogeneBiotech Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Allplex SARS-CoV-2 Assay	Seegene Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Q-Sens® COVID-19 Detection Kit V2	Cancer Rop Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	SGTi-flex COVID-19 IgM/IgG	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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Officially Approved by MFDS]			
S Korea [Diagnostic Devices Officially Approved by MFDS]	GenBody COVID-19 Ag	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™F COVID-19 Ag FIA	SD BIOSENSOR	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Real-Q Direct SARS-CoV-2 Detection Kit	BioSewoom, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay	Seegene Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™ F COVID-19 IgM/IgG Combo FIA	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Ezplex® SARS-CoV-2 Kit	SML GENETREE CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	BioCore 2019-nCoV Real Time PCR Kit	BioCore Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	BIOCREDIT COVID-19 Ag	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Humasis COVID-19 Ag Test	Humasis Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	LabGunTM COVID-19 ExoFast RT-PCR Kit	LabGenomics, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Dr. PCR™ Di20K COVID-19 Detection kit	OPTOLANE Technologies Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	U-TOP™ SARS-CoV-2 & Flu A/B	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Elecsys Anti-SARS-CoV-2	Roche Diagnostics Korea Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices]	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Siemens Healthineers Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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Officially Approved by MFDS]			
S Korea [Diagnostic Devices Officially Approved by MFDS]	GenBody COVID-19 IgM/IgG	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Humasis COVID-19 Ag Home Test	Humasis Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™ Q COVID-19 Ag Home Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	GeneFiner COVID-19 Fast RealAmp Kit	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	Real-Q SARS-CoV-2/FluA/FluB Detection Kit	BioSewoom, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	AccuPower® RV1 Real-Time RT-PCR Kit (RV1-1111)	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™ M nCoV Real-Time Detection kit	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Real-Q 2019-nCoV Detection kit	BioSewoom, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Q-Sens® COVID-19 Detection kit	Cancer Rop Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	U-TOPTM COVID-19 Detection Kit Plus	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Elecsys Anti-SARS-CoV-2	Roche Diagnostics Korea Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Siemens Healthineers Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	GenBody COVID-19 IgM/IgG	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices]	Humasis COVID-19 Ag Home Test	Humasis Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	STANDARD™ Q COVID-19 Ag Home Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	GeneFiner COVID-19 Fast RealAmp Kit	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Real-Q SARS-CoV- 2/FluA/FluB Detection Kit	BioSewoom, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	AccuPower® RV1 Real-Time RT-PCR Kit (RV1-1111)	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	cobas SARS-CoV-2 & Influenza A/BMolecular	Roche Diagnostics Korea Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	Humasis COVID-19 IgG/IgM Test	Humasis Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	R-FIND COVID-19 IgM ELISA	Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	R-FIND COVID-19 IgG ELISA	Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	R-FIND COVID-19 IgG/M/A ELISA	Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices Officially Approved by MFDS]	PaxView® SARS-CoV-2 real-time RT-PCR Kit Molecular	PaxGenBio Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	SGTi-flex COVID-19 Ag	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	AccuPower® RV1 Multiplex Kit (RV1-2112)	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices Officially Approved by MFDS]	careUS™ COVID-19 IgM/IgG Ab	WELLS BIO, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices]	PowerCheck™2019-nCoV RT PCR kit	kogenebiotech	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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for Export Only Approved by MFDS]			
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	AllplexTM2019-nCoV Assay	Seegene	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	DiaPlexQTMN Coronavirus Detection kit	SolGent Co.,Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	PCLMD nCoV one stop RT-PCR Kit	PCL, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices	LabGun™COVID-19 assay	LabGenomics,	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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for Export Only Approved by MFDS]			
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	Q-Sens 2019-nCoV detection Kit	Cancer Rop Co.,	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	STANDARD™Q COVID-19 IgM/IgG Duo Test	SD Biosensor,	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	GeneFinder COVID- 19 Plus RealAmp kit	OSANG Healthcare Co.,LTD	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	careGENE™ N-CoV RT-PCR kit	WELLS BIO, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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Export Only Approved by MFDS]			
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NeoPlex™COVID-19 Detection Kit	Genematrix Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SGTi-flex COVID-19 IgM	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SGTi-flex COVID-19 IgG	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export	Veri-Q PCR 316, nCoV-QS	MiCoBioMed,	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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Only Approved by MFDS]			
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	GenePro COVID-19 Detection Test	Gencurix Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	GenBody COVID-19 IgM/IgG	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	Humasis COVID-19 IgG/IgM Test	Humasis Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnost ic Devices for Export Only Approved by MFDS]	Dow QuickFinder™2019- nCoV Real time PCR	DowGene Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PCL COVID19 IgG/IgM Rapid Gold	PCL, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PCL COVID19 Ag Rapid FIA	PCL, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuPower COVID-19 Real-Time RT-PCR Kit (NCV-1111)	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuPower SARS-CoV-2 Real-Time RT-PCR Kit(SCV-2122)	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PaxView COVID-19 real-time RT-PCR Kit	PaxGenBio Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AFIAS COVID-19 Ab	Boditech Med	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MolecuTech® Real-Time COVID-19	YD Diagnostics CORP.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	LiliF™ COVID-19 Real-time RT-PCR Kit	iNtRON Biotechnology, Inc	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	1copy™COVID-19 qPCR Multi Kit	1drop Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Dow QuickFinder™-G 2019-nCoV Real time PCR	DowGene Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	careGENE™COVID-19 RT-PCR kit	WELLS BIO, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Isopolla COVID-19 detection kit(real-time)	M monitor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Isopolla COVID-19 detection kit(premix)	M monitor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	iLAMP Novel-CoV19 Detection Kit	iONEBIO inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BioCore 2019-nCoV Real Time PCR Kit	BioCore Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	TCM-Q Corona III kit	TCM Biosciences	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Kaira 2019-nCoV Detection Kit	OPTOLANE Technologies Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	RADI COVID-19 detection kit	KH Medical Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ichroma™COVID-19 Ab	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuraDTect™SARS-CoV-2 RT-qPCR kit	Genomictree, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit	Genesystem Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	JD COVID-19 qRT-PCR kit	Joonghun Pharmaceutical Co, Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	FREND COVID-19 IgG/IgM Duo	NanoEntek, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	WizDx™ COVID-19 CrystalMix PCR Kit	Wizbiosolutions Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BZ QPCR COVID-19 Kit	BioZentech, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BIOCREDIT COVID-19 Ag	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BIOCREDIT COVID-19 IgG+IgM Duo	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ExAmplar COVID-19 real time PCR	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Allplex™ SARS-CoV-2 Assay	Seegene Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LiliF™ COVID-19 Multi Real-time RT-PCR Kit	iNtRON Biotechnology, Inc	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	WizDx™ COVID-19 Real-time PCR Kit	Wizbiosolutions Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GenePro SARS-CoV-2 Test	Gencurix Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	U-TOP COVID-19 Detection Kit	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Gmate® COVID-19	Philosys Co.,Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Asan Easy Test COVID-19 IgG/IgM	Asan pharmaceutical Co., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Veri-Q, nCoV-OM	MiCoBioMed, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EU™COVID-19 Detection Kit	Eudipia	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LabGun™COVID-19 RT-PCR Kit	LabGenomics, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DLP™Q COVID 19 Real Detection Kit	DIOGENE Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	careUS™COVID-19 IgM/IgG	WELLS BIO, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	P4DETECT COVID-19 IgM/IgG	PRIME4DIA Co.,	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Dr. PCR 20K COVID-19 Detection Kit	OPTOLANE Technologies Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Axen™COVID-19 RT	Macrogen, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Accurate Rapid COVID-19 IgM/IgG Combo Test	HUMEDIX Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	COVID19+9G test™	Biometrix Technology, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CheKR™ COVID-19 IgM/IgG Rapid test	B-bio, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DIAKEY COVID-19 IgM/IgG Rapid Test	ShinJin Medics Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	ADTech COVID-19 IgM/IgG	ADTceh Co., LTD	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CTC™Q COVID-19 IgM/IgG Combo Test	CTCBIO INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SsmarTest COVID-19 IgM/IgG Detection Kit	SLSBio Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AllCheck COVID-19 IgG/IgM	CALTH Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	NowCheck COVID-19 IgM/IgG Test	BIONOTE, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NowCheck COVID-19 Ag Test	BIONOTE, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GG COVID-19 Quadplex Reverse Transcription Real Time Polymerase Chain Reaction Kit	GOODGENE Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DIAKEY REALcheck COVID-19(nCoV) Detection kit	ShinJin Medics Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEDIA W COVID-19 IgM/IgG	GREENCROSS MEDICAL SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEDIA W ONE COVID-19 IgM/IgG	GREENCROSS MEDICAL SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SMARTROL™ 2019- nCoV Detection Kit v1	GENECAST Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 Detection Kit	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	Epithod®616 COVID- 19 IgM/IgG Test kit	DxGen Corp.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuPower SARS-CoV-2 Multiplex Real-Time RT-PCR Kit	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	COVID-19 RT-qPCR PNA kit	TNS Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	KOVIcheck COVID-19 IgG/IgM	ProteomeTech Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PBCheck COVID-19 IgG/IgM	Precision Biosensor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	HB BestPlex™ COVID-19 RT-PCR	Heimbiotek Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NEXDia™ 2019-nCoV Detection Kit	Genes Laboratories	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Exdia COVID-19 IgG/IgM	Precision Biosensor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEDIA W COVID-19 Real-Time RT-PCR kit	GREENCROSS MEDICAL SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	En-swer COVID-19 RT-PCR	NanoEntek, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ichroma™ COVID-19 Ag	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LabGun™ COVID-19 Assay plus	LabGenomics, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Genelix™ COVID-19 Real-Time PCR Kit	Sanigen Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ACCEL ELISA COVID-19 Kit	Plexense, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Q-Sens COVID 19 IgG/IgM Rapid Kit	Cancer Rop Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DxReal COVID-19 Detection Kit	CALTH Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LabGun™ COVID-19 Fast RT-PCR Kit	LabGenomics, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AFIAS COVID-19 Ag	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Absoludy COVID-19 IgM/IgG Rapid	Absology Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Nano-KGIC COVID-19 IgM/IgG Kit	NanoBioLife Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Real-Q Direct SARS-CoV-2 Detection Kit	BioSewoom, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PROTAN COVID-19 IgM/IgG	PROTANBIO Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MDGen-AB96 COVID-19 IgG	MicroDigital Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	R-FIND COVID-19 IgG ELISA	SG Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	AQ-TOP™ COVID-19 Rapid Detection Kit	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Ezplex® SARS-CoV-2 FAST G Kit	SML GENETREE CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CareStart™ COVID-19 IgM/IgG	AccessBioKorea	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LiliF™ GBN COVID-19 IgG Rapid Kit	iNtRON Biotechnology, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	iDetect™ SARS-CoV-2 Detection Kit	COSMAX PHARMA Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LAMplex RT-qLAMP COVID-19 Detection Assay	CellSafe Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AnyLab COVID-19 IgM/IgG Test Kit	Z Biotech Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EuDX™ COVID-19 Multiplex Detection Kit	Eudipia	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GenBody COVID-19 Ag	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD™ Q COVID-19 IgM/IgG Combo Test(Q-NCOV-01C)	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Palm PCR™ COVID-19 Fast Real-time RT-PCR Kit	ACEBiomed, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEdania COVID-19 qRT-PCR	ProteomeTech Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	MDx® COVID-19 Ab Rapid Test	MEDIAN DIAGNOSTICS INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	KORA COVID19 IgM/IgG	MediHelpLine Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PCL COVID19 Speedy RT-PCR	PCL, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	findGENE™ COVID-19 RT-PCR kit	WOORIDUL PHARMACEUTICAL LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	findGENE™ N-CoV RT-PCR kit	WOORIDUL PHARMACEUTICAL LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 IgG/IgM Rapid Test	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	R-FIND COVID-19 IgG/M/A ELISA	SG Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GenBody Influenza/COVID-19 Ag Multi	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	A+CheQ COVID-19 High-Speed RT-qPCR Detection Kit	AMSBIO	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	VERI-Q COVID-19 IgG/IgM Rapid Test	MiCoBioMed, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ElsiQ™ 2019-nCoV Detection Kit	EONE Life Science Institute	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BZ COVID-19 IgM/IgG	BioZentech, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BZ IsoMDx COVID-19 kit	BioZentech, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEDIA W COVID-19 Colorimetric LAMP premix kit	GREENCROSS MEDICAL SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AQ-TOP™ COVID-19 Rapid Detection Kit Plus	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	R-FIND COVID-19 IgM ELISA	SG Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BIOCREDIT COVID-19 IgG/IgM Combo	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Wonmed Covid-19 IgM/IgG	WON Medical Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Ezplex® SARS-CoV-2 G Kit	SML GENETREE CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Veri-Q nCoV-QM-N	MiCoBioMed, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NGenePlex™ nCoV qRT-PCR kit	NGeneBio Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	findUS™ COVID-19 IgM/IgG	WOORIDUL PHARMACEUTICAL LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SGT Anti-SARS-CoV-2 Total Ab ELISA	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD™ E COVID-19 Total Ab ELISA	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	1copy™ COVID-19 qPCR Triplex Kit	1drop Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GenePro COVID-19 IgG/IgM Test	Gencurix Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Rapid COVID-19 PoaCheck	BIOPOA Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SGTi-flex COVID-19 Ag	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MDGen CL96-COVID-19 IgG	MicroDigital Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CHEXEL COVID-19 IgM/IgG	NB POSTECH, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	IVDLAB COVID-19 IgG/IgM Test	IVDLab Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuFind COVID19 IgG, AllCheck COVID-19 IgG	CALTH Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEDIA W COVID-19 AG	GREENCROSS MEDICAL SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ACEBiomed COVID-19 IgM/IgG	ACEBiomed, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CD COVID-19 assay Kit	CHUNGDO PHARM. CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Sampinute™ COVID-19 Antigen MIA	BBB Inc	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MARK-BTM COVID-19 Ag	BBB Inc	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD™ M nCoV Real-Time Detection kit	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MDGen AB96-COVID-19 IgM	MicroDigital Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GeneFinder COVID-19 Fast RealAmp kit	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Humasis COVID-19 Ag Test	Humasis Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	FREND COVID-19 SP	NanoEntek, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GBT COVID-19 RAPID KIT	GloryBiotech corp.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	IMMUNEMED COVID-19 IgM/IgG RAPID	ImmuneMed Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Exdia COVID-19 Ag	Precision Biosensor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 & Flu Combo Kit	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Asan qPCR Test COVID-19	Asan pharmaceutical Co., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	TCM-Q SARS-CoV-2 Real-time PCR Kit	TCM Biosciences Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	InstaView COVID-19 IgG/IgM	SG Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EuGenoQ™ COVID 19 RT PCR Kit	EUBIOLOGICS CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DLPTMQ COVID19 RT-LAMP Kit	DIOGENE Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AdvanSure™ SARS-CoV-2 IgG(S1) ELISA	LG Chem, Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	Panbio™ COVID-19 Ag Rapid Test Device	Abbott Diagnostics Korea Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Absolusy COVID19 IgM/IgG Combo	Absology Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	QPLEXTM COVID-19 test	QUANTAMATRIX Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PowerChekTM SARS-CoV-2 Influenza A&B RSV Multiplex Real-time PCR kit	KogeneBiotech Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AllplexTM SARS-CoV-2/FluA/FluB/RSV Assay	Seegene Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NeoPlex™ FluCOVID Detection Kit	Genematrix Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BIOCREDIT CoviFlu Ag Duo	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	FREND COVID-19 Ag	NanoEntek, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NOW Detect COVID-19 IgM/IgG Rapid Test	COSMAX PHARMA Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	OHC SARS-CoV-2 IgG/IgM Combo Test	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AllCheck COVID19 Ag	CALTH Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BUZZARTM SARS-CoV-2 IgG/IgM	Rmedica Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	P4DETECT COVID-19/Flu	PRIME4DIA Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	P4DETECT COVID-19 Ag	PRIME4DIA Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Palm PCRTM Fast COVID-19 Assay	ACEBiomed, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 Ag Test	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MmaxTM SARS-CoV-2 Detection Kit Molecular	M monitor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Asan Easy Test COVID-19 Ag Antigen	Asan pharmaceutical Co., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEDIA Quantum COVID-19 Ag Antigen	GREENCROSS MEDICAL SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuPower RV1 Multiplex Kit Molecular	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuPower RV1 Real-Time RT-PCR Kit Molecular	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AccuPower COVID-19 Multiplex Real-Time RT-PCR Kit Molecular	BIONEER Corporation	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ExAmplex Influenza A/B SARS-CoV-2 PCR Kit Molecular	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SGTi-flex COVID-19 & Flu A/B Ag DUO Antigen	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD M Flu/SARS-CoV-2 Real-time Detection kit	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	U-TOPTM SARS-CoV-2 & Flu A/B	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	IVDLAB COVID-19 Ag Test Antigen	IVDLab Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 & Flu Duo Test	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	careUSTM COVID-19 antigen	WELLS BIO, INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DIAKEY COVID-19 Ag Rapid Test	ShinJin Medics Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARDTM Q COVID/Flu Ag Combo Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PBCheck COVID-19 Ag Antigen	Precision Biosensor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARDTM F COVID/Flu Ag Combo FIA	SD Biosensor, Inc	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	INFINA 2019_nCoV Real-time RT-PCR kit	Biowithus, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Epithod 616 COVID-19 IgG Test Kit	DxGen Corp.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MDx COVID-19 Ag Rapid Test	MEDIAN DIAGNOSTICS INC.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NanoCare™ COVID-19 Antigen Kit	NanoBioLife Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	FRENDTM COVID-19+FLU A&B	NanoEntek, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AnyLab COVID-19 Ag Test Kit	Z Biotech Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	1copy COVID-19 qPCR 4plex Kit	1drop Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EuSeroQ™ COVID-19 IgM/IgG Rapid Kit	EUBIOLOGICS CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	RADI COVID-19 Ag Rapid Test	KH Medical Co.,Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GeneFinder COVID-19 Ag Rapid Test	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GeneFinder COVID-19/Flu A&B RealAmp Kit	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BioCore COVID-19 Fast Real Time PCR Kit	BioCore Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Asan Easy Test Flu/COVID-19 Ag Combo	"Asan	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	pharmaceutical Co., LTD."		For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CareStart™ COVID-19 Antigen	AccessBioKorea	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BZ COVID-19 Ag Test	BioZentech, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	VERI-Q COVID-19 Ag Rapid Test	MiCoBioMed, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AFIAS COVID-19/Flu Ag Combo	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ichroma™ COVID-19/Flu Ag Combo	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Direct Dr. PCRTM SARS-CoV-2 Detection Kit	"OPTOLANE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Technologies Inc."		For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Absoludy COVID-19 Ag Rapid	Absology Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GenBody Influenza/COVID-19 Ag Triple	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PCLMA ABC multi RT-PCR Kit	PCL, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Q-Sens® COVID-19 Detection kit v2	Cancer Rop Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	findUSTM COVID-19 Antigen	"WOORIDUL	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PHARMACEUTICAL LTD."		For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AMB COVID-19 Ag	ACEBiomed, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GenBody FIA COVID-19 Ag	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Exdia Multiplex COVID-19 & flu	Precision Biosensor Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PCL COVID 19 Ag Gold	PCL, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CareStart™ COVID-19 Antigen	AccessBioKorea	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CD COVID-19 Ag assay Ki	CHUNGDO PHARM. CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	InstaView COVID-19 Antigen	SG Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DiNonA COVID-19 Ab IgM/IgG	DiNonA, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	DiaPlexQTM COVID-19 (N, ORF1a) Detection Kit	SolGent Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CHEXELTM COVID-19 Ag	NB POSTECH, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 & Flu Duo Plus	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	RADI COVID-19 IgG/IgM Rapid Test	KH Medical Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	RADI Flu-SC2 Ag Rapid Test	KH Medical Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Panbio™ COVID-19 Ag Rapid Device (41FK11)	Abbott Diagnostics Korea Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Dow NETPlex™ SARS-CoV-2 RT-PCR Kit	DowGene Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Ezplex® SARS-CoV-2/RV G Kit	SML GENETREE CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	KGIC™ COVID-19 Antigen (Ag) Kit	Korea Genome Information Institute	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GENEdania SARS-CoV-2/Flu A/Flu B Fast qRT-PCR	ProteomeTech Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MARK-BTM COVID-19 Ag	BBB Inc	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BIOCREDIT COVID-19 IgG	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MAUVE™ COVID-19 Ag, SARS-CoV-2 Ag Test	InTelos Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	WEMED™ COVID-19 Antigen (Ag) Test	YOUNG WOO SCIENCE	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	INO SARS-CoV-2 Detection Kit	Inogenix Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AFIAS COVID-19 nAb Antibody	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	KNAX-SMART SARS-CoV-2 IgM/IgG	KNAX Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Gmate® COVID-19 Ag	Philosys Co.,Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SsmarTest COVID-19 Ag Detection Kit	SLSBio Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EDT™ COVID-19 Ag Rapid Card	EzDiaTech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	KGIC™ COVID-19 RT-LAMP Pro kit	Korea Genome Information Institute	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EuViroQ™ COVID-19 Ag Rapid Kit	EUBIOLOGICS CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ND COVID-19 Multi Kit	NDFOS Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	KNAX-SMART SARS-CoV-2 Ag	KNAX Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	KNAX-SMART SARS-CoV-2, Influenza A&B Ag Combo	KNAX Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	RADI Flu-SC2 Detection Kit	KH Medical Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PaxView® SARS-CoV-2 MPCR-ULFA Kit	PaxGenBio Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	KDx-SARS-CoV-2 (SM) LAMP RT-PCR Kit	K-BioCELL Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	EDGC™ COVID-19 Ag Test	NB POSTECH, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Veri-Q COVID-19 ELISA Kit	MiCoBioMed, Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	iFinDx COVID-19 IgM/IgG	GenBody Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	IVDLAB COVID-19 & Influenza Combo	IVDLab Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	STANDARD™ easy Q COVID-19 Ag Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	COVID-19 IgG Cartridge	I-SENS, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	1copy™ COVID-19/FluA/FluB/RSV qPCR Kit	1drop Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Asan Easy Test COVID-19 IgG/IgM (N)	Asan pharmaceutical Co., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Absology Co., Ltd.	Absoludy COVID-19 Ag	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Seegene Inc.	Allplex™ SARS-CoV-2/Flu/RSV Assay	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	ADTceh Co., LTD	ADTech COVID-19 Ag RAPID KIT	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Korea Genome Information Institute	KGIC™COVID-19 IgM/IgG Kit	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	AddBioMeditek Co.	AddMedi SARS-CoV-2 RT-qPCR Kit	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SSa-19/A&B	SeaSun Biomaterials	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	REF:CFPC-120, ichroma™ COVID-19 nAb	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Axen™ COVID-19 IgM/IgG RAPID	MacroGen, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GBT COVID-19 Ag RAPID KIT	GloryBiotech corp.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	EDT™ COVID-19 IgG/IgM Rapid Card	EzDiaTech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	COVID-19 IgM/IgG Cartridge	I-SENS, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SARS-CoV-2 Rapid Antigen Test Nasal	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	Kaira™ COVID-19/Flu Detection Kit	OPTOLANE Technologies Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	PowerChek™ SARS-CoV-2 Advanced Real-time PCR Kit	KogeneBiotech Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Epithod®616 COVID-19 Ag Test Kit	DxGen Corp.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD™ M SARS-CoV-2	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	CHAMP COVID-19 Multiplex Kit	KH Medical Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NOW Detect COVID-19 Antigen Rapid Test	COSMAX PHARMA Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	LiliF™ GBN COVID-19 Ag Rapid Kit	iNtRON Biotechnology, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Ezplex® SARS-CoV2/RV Fast G Kit	SML GENETREE CO., LTD.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	R-FIND SARS-CoV-2 Neutralizing Antibody ELISA	SG Medical, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	IMMUNEMED COVID-19 Ag RAPID	ImmuneMed Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	BIOCREDIT COVID-19 Ag Test Nasal	RapiGEN, INC	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DiaPlexQ™ Flu A/B & SARS-CoV-2 Detection Kit	SolGent Co., Ltd	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	HB BestPlex™ 3C COVID-19 RT-PCR Kit	Heimbiotek Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Allplex™ SARS-CoV-2 Variants I Assay	Seegene Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Allplex™ SARS-CoV-2 Master Assay	Seegene Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	COVICHEK™ COVID-19 Ag Kit	WIZCHEM Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NEXdia™ COVID-19 & Influenza A/B Detection kit	Genes Laboratories	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	HBelisa™ SARS-CoV-2 Neutralizing Antibody Detection Kit	HB Healthcare Corp.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD™ Q COVID-19 Ag Home Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Axen™ COVID-19 Ag RAPID	Macrogen, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SGT SARS-CoV-2 In Vitro Neutralizing Antibody Test (IVnAT)	Sugentech, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	MDGen AB96-COVID-19 dual IgG	MicroDigital Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Humasis COVID-19 Ag Home Test	Humasis Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	WonMed Covid-19 Ag	WON Medical Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	SARS-CoV-2 Easy Kit (Real-time PCR)	SGENEBIO	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	THERAGEN COVID-19 ASSAY	THERAGEN GENOMECARE CO., LTD	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	NEXdia™ COVID-19 & Influenza A/B Detection kit(For ABI 7500)	Genes Laboratories	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Panbio™ COVID-19 Antigen Self-Test	Abbott Diagnostics Korea Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	STANDARD™ i-Q COVID-19 Ag Home Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	GeneFinder COVID-19 Ag Plus Rapid Test	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Genoplan SARS-CoV-2 Assay	Genoplan Korea, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	QPLEX™ COVID-19 Test	QUANTAMATRIX Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	WizDx™ COVID-19 CrystalMix® Multi PCR Kit	Wizbiosolutions Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	DirectFast™ SARS-CoV-2 multiplex assay	NanoHelix Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Grace Tree COVID-19 IgM/IgG	Korea Heavy Industry and Development Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Grace Tree COVID-19 Ag	Korea Heavy Industry and Development Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	Boditech Quick™ COVID-19 Ag	Boditech Med Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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S Korea [Diagnostic Devices for Export Only Approved by MFDS]	HB BestPlex™ 3C Flu/COVID-19 RT-PCR Kit	Heimbiotek Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	STANDARD™ Q COVID-19 Ag Saliva Test	SD Biosensor, Inc.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only Approved by MFDS]	KNAX-SMART SARS- CoV-2 IgM/IgG (N)	KNAX Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do
S Korea [Diagnostic Devices for Export Only	GeneFinder™ COVID- 19 & Flu Duo Rapid Test	OSANG Healthcare Co., Ltd.	For updated information on all products listed by the MFDS use this link: https://www.mfds.go.kr/eng/brd/m_65/list.do

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China	Antibody test kit for novel coronavirus 2019-nCoV (chemiluminescence microparticle immunoassay)	Xiamen Innodx Biotech Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Guangzhou Wondfo Biotech Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	INNOVITA(Tangshan) Biological Technology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	IgG Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)	Bioscience (Chongqing) Diagnostic Technology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	IgM antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Hecin Scientific, Inc.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	IgM Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)	Bioscience (Chongqing) Diagnostic Technology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg

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China	IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Nanjing Vazyme Medical Technology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)	Zhuhai Livzon Diagnostics Inc.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (combinatorial probe-anchor synthesis sequencing)	BGI Biotechnology(Wuhan) Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Dual amplification)	Wuhan Zhongzhi Biotechnologies INC.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Beijing Applied Biological Technologies Co., Ltd	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	BGI Biotechnology (Wuhan) Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg

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China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Da An Gene Co., Ltd.	For updated information on all products listed by the NMPA use this link https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Maccura Biotechnology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Sansure Biotech Inc.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai BioGerm Medical Biotechnology Co., Ltd	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai Fosun Long March Medical Science Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Shanghai GeneoDx Biotechnology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel	Shanghai ZJ Bio-Tech Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXIXJbE95hp0gcqsqj3Sg

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	coronavirus 2019-nCoV (fluorometric PCR)		
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)	Wuhan Easy Diagnosis Biomedicine Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (hybridization capture immunofluorescence)	Anbio (Xiamen) Biotechnology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Isothermal amplification-real time fluorometric PCR)	Ustar Biotechnologies (Hangzhou) Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA capture probe method)	Shanghai Rendu Biotechnology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
China	Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA isothermal amplification lateral flow assay)	Wuhan Zhongzhi Biotechnologies INC.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg

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China	Nucleic Acid reagent test kit for six respiratory viruses (constant temperature amplification chip)	Chengdu CapitalBio Biotechnology Co., Ltd.	For updated information on all products listed by the NMPA use this link: https://mp.weixin.qq.com/s/8nXlXJbE95hp0gcqsqj3Sg
Russia	Refer to link	Refer to link	For updated information on all products listed by Roszdravnadzor use this link: https://www.rozdravnadzor.ru/services/misearch or https://medvestnik.ru/chronicles/Odobrennye-testy-COVID.html
EU	Refer to link	Refer to link	For updated information on all products listed by the EU use this link: https://covid-19-diagnostics.jrc.ec.europa.eu/devices#form_content