

WHO list of prequalified in vitro diagnostic products

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 5 June 2024

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Application Number and Link to the Public Report
2024	HIV NAT	Alinity m HIV-1	08N45-090	CE-marked	Abbott Molecular Inc.	1300 East Touhy Avenue, Des Plaines, IL 60018 USA	48 T/kit	PDQx 0640-027-00 (Public Report to be posted soon)
2024	Malaria RDT	ONE STEP Malaria (P/Fv) Tri-line Test	ITPW11009-TC25, ITPW11009-TC40	RoW	IntTec PRODUCTS, Inc	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	25 T/kit 40 T/kit	PDQx 0627-017-00 (Public Report to be posted soon)
2024	Malaria RDT	One Step Malaria (P) Test	ITPW11007-TC25, ITPW11007-TC40	RoW	IntTec PRODUCTS, Inc	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	25 T/kit 40 T/kit	PDQx 0626-017-00 (Public Report to be posted soon)
2024	HIV NAT	Xpert HIV-1 Qual XC	GXHIV-QA-XC-CE-10	CE-marked	Cepheid AB	Cepheid AB located at Röntgenvägen 5 Solna, 17127, Sweden	10 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-xpert-hiv-1-qual-xc-pqdr-0362-070-00
2023	HCV RDT	First Response HCV Card Test	P03FRCS, P03FRCS0, and P03FRFC100	RoW	Premier Medical Corporation Private Limited	Premier Medical Corporation Ltd., at A1-302 and 3702 to 3705 and 3805 to 3805 W/2 and W/3, GIDC Sarigam 396155, Gujarat, India	25 T/kit, 50 T/kit, 100 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-first-response-hcv-card-test-pqdr-0469-010-00
2023	HIV NAT	cobas HIV-1/HIV-2 Qualitative nucleic acid tests for use on the cobas 6800/8800 and cobas HIV-1/HIV-2 Qualitative Nucleic acid test for use on the cobas 5800/6800/8800 Systems	07862113190, and 09040528190	CE-marked	Roche Molecular Systems, Inc.,	Roche Molecular Systems, Inc., located at 1080 US Hwy 302 South Branchburg Township, 8879, United States of America	96 T/kit, 192 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-hiv-1-hiv-2-qual-0628-046-00
2023	HCV RDT	HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma)	HC-402WA, HC-402WB, HC-402WC, and HC-402WD	RoW	ABON Biopharm (Hangzhou) CO.,LTD	Abon Biopharm (Hangzhou) CO.,LTD. located 198# 12th Street East, Economic and Technological Development Area, 310018 Hangzhou, China	40 T/kit 25 T/kit 25 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-hcv-hepatitis-c-virus-rapid-test-device-whole-blood-serum-plasma-pqdr-0387-051-00
2023	HIV NAT	SAMBA II HIV-1 Qual Whole Blood Test	4500-12	CE-marked	Diagnostics for the Real World Ltd	Diagnostics for the Real World in San Jose, CA, USA	12 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-samba-ii-hiv-1-qual-whole-blood-test-pqdr-0458-072-00
2023	HPV Virological Technologies	cobas HPV	07460151190, 07460171190, 07002238190, 069975461190, 06997511190, 06997538190, 06997503190	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	480 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-hpv-pqdr-0468-046-00
2022	Syphilis RDT	Determine Syphilis TP	7D2452, 7D2453 and 7D2453SET	RoW	Abbott Diagnostics Medical Co., Ltd.	Abbott Diagnostics Medical Co., Ltd. located at 357 Matsuhai, Chiba-ken Matsudo-shi, 270-2214, Japan	30 T/kit 100 T/kit 100 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-determine-syphilis-tp-pqdr-0485-013-00
2022	HCV NAT	Xpert HCV VL Fingerstick	GDXHC-VF-CE-10	CE-marked	Cepheid AB	Röntgenvägen 5, SE-171 54 Solna, Sweden	10 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-xpert-hcv-vl-fingerstick-pqdr-0453-070-00
2022	HIV RDT	FaHiv Verification Test	29011-W20 29011AW20	RoW	Abbott Rapid Diagnostics Jena GmbH	Orlweg 1, Jena, Germany	20 T/kit 20 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-fahiv-verification-test-pqdr-0480-012-00
2022	Malaria RDT	One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	RFWMPH-02, RFWMPH-03, RFWMPH-04	RoW	Meril Diagnostics Pvt. Ltd	Second Floor, D1-03, Meril Park, Survey No 135/2/B & 17A/2, Multanand Marg, Chail, Vapi, 396291, India	10 T/kit 25 T/kit 50 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-malaria-pf-hrp-ii-ag-pqdr-0410
2022	HIV NAT	cobas HIV-1 Nucleic acid test for use on the cobas 4800 System	0879292190, 06979572190,	CE-marked	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit; 10 Sets;	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-hiv-1-nucleic-acid-test-use-cobas-4800-system-pqdr-0710-118-00
2022	HIV RDT for self testing	Wondfo HIV Self-Test	W006P0050, W006P0059, and W006P0060	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lishikan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	1 T/kit; 20 T/kit 100 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-wondfo-hiv-self-test-pqdr-0357-004-01
2022	HIV RDT for self testing	CheckNOW HIV SELF TEST	29012-W01	RoW	Abbott Rapid Diagnostics Jena GmbH	Loebstedter Str. 103-105, Jena, Germany	1 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-checknow-hiv-self-test-pqdr-0481-012-00
2022	HIV RDT	TrinScreen HIV	5551100	RoW	Trinity Biotech Manufacturing Ltd	1 Southern Cross IDA Business Park in Bray, Ireland	100 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-trinscreen-hiv-pqdr-0471-052-00
2021	HCV NAT	¶ cobas HCV (Quantitative nucleic acid test for use on cobas 5800/6800/8800 Systems)	6997732190 09040761190	CE-marked	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-hvcobas-5800x-0465-046-00
2021	Syphilis RDT	First Response Syphilis Anti-TP Card Test	P03FRCS, P03FRCS0, P03FRFC100, P03FRCS-SA	RoW	Premier Medical Corporation Private Limited	Site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India Site 2: J2-35A, Shree Ganesh Industrial Estate, Kachigam, Nash Daman, Daman 396215, India.	25 T/kit 50 T/kit 100 T/kit 25 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-first-response-syphilis-anti-tp-card-test-pqdr-0471-010-00
2020	HIV NAT	¶ cobas HIV-1 Quantitative nucleic acid test for use on the cobas 5800/6800/8800 Systems	07000991190 09040801190	CE-marked	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-5800x-0800-0800-systems-pqdr

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2020	HIV RDT	# MERISCREEN HIV 3-2 WB	HVWRPD-01 HVWRPD-02 HVWRPD-06 HVWRPD-07 HVWRPD-08 HVWRPD-09 HVWRPD-10 HVWRPD-11 HVWRPD-12	CE-marked	Meril Diagnostics Pvt. Ltd.	Second Floor, 01-03, Meril Park, Survey No 135/2/B & 174/2, Multanand Marg, Chala, Vapi, 396191, India	30 T/kit 40 T/kit 50 T/kit 10 T/kit 100 T/kit 25 T/kit 30 T/kit 40 T/kit 60 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-meriscreen-hiv-3-2-wb-pdq-0464-074-00
2020	Malaria RDT	Paracheck PF - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	302030025, 302030005, 302030010, 302030025, 302030100, 302030025(1T)	CE-marked	Orchid Biomedical Systems – A Division of Tulp Diagnostics (P) Ltd	Plot nos 88/89, Phase I C, Verna Industrial Estate, Verna, Goa, 403722, India	1T/kit, 5 T/kit 10 T/kit 25 T/kit 100 T/kit 25 x 1 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-paracheck-of-rapid-test-falciparum-malaria-device-ver-3-pdq-0121-024-00
2020	Malaria RDT	One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02, MHLRPD-03, MHLRPD-04, MHLRPD-05.	CE-marked	Meril Diagnostics Pvt. Ltd	Second Floor, 01-03, Meril Park, Survey No 135/2/B & 174/2, Multanand Marg, Chala, Vapi, 396191, India	30 T/kit 10 T/kit 25 T/kit 50 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-one-step-test-malaria-pfpan-ag-meriscreen-malaria-pfpan-ag-pdq-0110-074-00
2020	CD4 Technologies	VISITECT CD4 Advanced Disease	AB376	CE-marked	AccuBio Ltd	AccuBio Ltd located at Hillforts Business, Village, Alva, FK12 5DQ United Kingdom.	25 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-visitect-cd4-advanced-disease-pdq-0384-077-00
2020	HIV RDT	STANDARD Q HIV 1/2 Ab 3-Line Test	09HV200; 09HV300M	RoW	SD Biosensor, Inc	site 1: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. site 2: Plot no. 38, Sector 4, IMT Manesar, Gurugram, Haryana 122052, India.	25 T/kit; 25 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-standard-q-hiv-1-2-ab-3-line-test-pdq-0383-117-00
2020	Malaria RDT	parascreeen - Rapid test for Malaria Pan/Pf	503030025(1T) 503030010; 503030025; 503030050; 503030100	CE-marked	Zephyr Biomedicals – A Division of Tulp Diagnostics (P) Ltd.	M46-47, Phase III B, Verna, Goa, 403722, India	25 x 1 T/kit 10 T/kit 25 T/kit 50 T/kit 100 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-parascreeen-rapid-test-malaria-pan-pf-pdq-0291-035-00
2020	Malaria RDT	FalcoVax - Rapid test for Malaria Pv/Pf	503010025(1T) 503010010; 503010025; 503010050; 503010100	CE-marked	Zephyr Biomedicals – A Division of Tulp Diagnostics (P) Ltd.	M46-47, Phase III B, Verna, Goa, 403722, India	25 x 1 T/kit 10 T/kit 25 T/kit 50 T/kit 100 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-falco-vax-rapid-test-malaria-pv-pf-pdq-0290-025-00
2020	HIV/Syp RDT	STANDARD Q HIV/Syphilis Combo Test	09HV200	RoW	SD Biosensor, Inc	site 1: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. site 2: Plot no. 38, Sector 4, IMT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/pqweb/WHOIPR/public-report-standard-q-hiv-syphilis-combo-test-pdq-0382-117-00
2020	HCV NAT	Alinity m HCV	08NS0-090; 08NS0-080; 08NS0-070	CE-marked	Abbott Molecular Inc	1300 East Touhy Avenue, Des Plaines, IL 60018 USA	4 trays of 48 T/kit 12 tubes of each control 4 tubes x 1.85 mL	https://extranet.who.int/prequal/WHOIPR/public-report-ality-m-hcv-pdq-0461-027-00
2020	Malaria RDT	STANDARD Q Malaria P.F/P-v Ag Test	09MAL200	CE-marked	SD Biosensor, Inc.	site 1: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. site 2: Plot no. 38, Sector 4, IMT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-standard-q-malaria-pf-pv-ag-test-pdq-0348-117-00
2020	Malaria RDT	STANDARD Q Malaria P.F Pan Ag Test	09MAL300	CE-marked	SD Biosensor, Inc.	site 1: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. site 2: Plot no. 38, Sector 4, IMT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-standard-q-malaria-pf-pan-ag-test-pdq-0347-117-00
2020	Malaria RDT	STANDARD Q Malaria P.F Ag Test	09MAL100	CE-marked	SD Biosensor, Inc.	site 1: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. site 2: Plot no. 38, Sector 4, IMT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-standard-q-malaria-pf-ag-test-pdq-0346-117-00
2020	HCV RDT	STANDARD Q HCV Ab Test	09HCV100	RoW	SD Biosensor, Inc.	site 1: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. site 2: Plot no. 38, Sector 4, IMT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-standard-q-hcv-ab-test-pdq-0360-117-00
2020	HCV EIA	Monolisa HCV Ag Ab ULTRA V2	72561 and 72562	CE-marked	Bio-Rad	1, bd Raymond Poincaré, 92430, Marie La Coquette, France and Route de Cassel, 59114, Steenvoorde, France	96 T/kit 480 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-monolisa-hcv-ag-ab-ultra-v2-pdq-0139-031-00
2019	HCV NAT	Abbott RealTime HCV	4186-90, 4186-80, 4186-70 and 4186-10.	CE-marked	Abbott Molecular Inc	1300 East Touhy Avenue, Des Plaines, IL 60018 USA	96 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-abbott-realtime-hcv-pdq-0450-027-00
2019	HIV RDT for self testing	SURE CHECK HIV Self-Test	60-9508-0	RoW	Chembio Diagnostic Systems, Inc	3661 Horseblock Road, Medford, NY 11763 USA	1 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-sure-check-hiv-self-test-pdq-0054-006-01
2019	HPV Virological Technologies	Abbott RealTime High Risk HPV	02N09-092; and 02N09-080	CE-marked	Abbott GmbH	Max Planck-Ring 2, Wiesbaden, 65205, Germany	96 T/kit	https://extranet.who.int/prequal/WHOIPR/public-report-abbott-realtime-high-risk-hpv-pdq-0455-180-00

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2019	HIV RDT	First Response HIV 1-2.0 Card test (Version 2.0)	P05FR005; P05FR010; P05FR025; P05FR030; P05FR050; P05FR060; P05FR100	RoW	Premier Medical Corporation Private Limited	A1-302, GIDC, Sarigam, India	5 T/kit 10 T/kit 25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-first-response-hiv-1-2-0-card-test-pqds-0363-010-00
2019	HBsAg RDT	Determine HBsAg 2	702942; 702943; 702943 SET	RoW	Abbott Diagnostics Medical Co.Ltd	357 Matsuhidai, Matsudo-shi, 270-2214, Chiba-ken, Japan	20 T/kit 100 T/kit 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-determine-hbsag-2-pqds-0451-013-00
2019	HCV EIA	ARCHITECT HCV Ag assay	6647-29, 6647-11; 6647-02, and 6C39-01	CE-marked	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Gosens-shi, Niigata, Japan	100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-architect-hcv-ag-assay-pqds-0374-130-00
2019	HIV RDT for self testing	Mylan HIV Self Test	ARST001-03; ARST001-09-01; ARST001-09-02; ARST001-09-03	RoW	Atomo Diagnostics Pty. Ltd	Site 1: Atomo Diagnostics Pty Ltd at Level 2, 701-703 Parramatta Road, Leichardt 2040 NSW, Australia Site 2: Lateral Flow Laboratories (LFL) at Unit 1 & 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Mulzenberg, 7945, South Africa	1 T/kit, 1 T/kit, 1 T/kit, 1 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-mylan-hiv-self-test-pqds-0320-090-00
2019	HIV/SyP RDT	First Response HIV1-2/Syphilis Combo Card Test	I20FR025; I20FR030; I20FR050; I20FR060; I20FR100	RoW	Premier Medical Corporation Private Limited	Sarigam, Gujarat, India	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-first-responder-hiv1-2-syphilis-combo-card-test-pqds-0364-030-00
2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40 ITPW02153-TC25 ITPW02153-TC40 ITPW02153-TC40SA ITPW02154-TC40	RoW	IntEC PRODUCTS, INC	305, Wangjiao Rd, Xinying RD. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit 40 T/kit 40 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-one-step-anti-hiv-1-2-test-pqds-0372-017-00
2019	HCV RDT	Rapid Anti-HCV Test	ITPW01152-TC40; ITPW01152-TC25; ITPW01153-TC40	RoW	IntEC PRODUCTS, INC	305, Wangjiao Rd, Xinying RD. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-rapid-anti-hcv-test-pqds-0373-017-00
2019	Malaria RDT	AdvOx Malaria Pf Rapid Malaria Ag Detection Test	00 DKM RK-MAL-ADK-004-001, 00 DKM RK-MAL-ADK-004-025, 00 DKM RK-MAL-ADK-004-030, and 00 DKM RK-MAL-ADK-004-050	RoW	Advy Chemical Pvt Ltd.,	Plot No.A-334,336,338 & A-337 & 339 Road no. 25 & 26, Wagle Industrial Estate Thane 400 604 India	1 T/kit, 10 T/kit, 25 T/kit, 50 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-advox-malaria-pf-rapid-malaria-ag-detection-test-pqds-0345-101-00
2019	Malaria RDT	NtTek Eliminate Malaria Pf and and NtTek Malaria Pf	05FK140; 05FK141; 05FK142; 05FK143	CE-marked	Abbott Diagnostics Korea Inc	Site 1: 46, Hagul-ro 15 beongil, Gilheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea Site 2: 62, Borahagil-ro, Gilheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	257/kit; 257/kit; 17/kit x 25 each; 17/kit x 25 each	https://extranet.who.int/prequal/WHOPR/public-report-ntek-eliminate-malaria-pf-pqds-0349-012-00
2019	HIV NAT	m-PIMA HIV 1/2 VL	27015-W50	RoW	Abbott Rapid Diagnostics Jena GmbH	Orlweg 1, D-07743 Jena, Germany	50 cartridges/kit	https://extranet.who.int/prequal/WHOPR/public-report-m-pima-hiv-1-2-vl-pqds-0359-032-00
2018	Malaria RDT	First Response Malaria Antigen P. falciparum (HRP2) Card Test	P13FR025; P13FR030; P13FR035; P13FR030	RoW	Premier Medical Corporation Limited	Site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; Site 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	25 + single kit; 10 + single kit; 25 + multi kit; 30 + multi kit	https://extranet.who.int/prequal/WHOPR/public-report-first-responder-malaria-antigen-p-falciparum-hrp2-card-test-pqds-0344-010-00
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	P15FR010; P15FR025; P15FR030; P15FR025	RoW	Premier Medical Corporation Limited	Site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; Site 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	10 + single test; 25 + single test; 30 + multi test; 25 + multi test	https://extranet.who.int/prequal/WHOPR/public-report-first-responder-malaria-ag-pf-pv-card-test-pqds-0349-010-00
2018	Malaria RDT	Bioline Malaria Ag P.f./P.v	05FK120; 05FK123	CE-marked	Abbott Diagnostics Korea Inc	65 Borahagil-ro, Gilheung-gu, Yongin-si, Geonggi-do, South Korea	257/kit; 17/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-malaria-ag-pf-pv-pqds-0352-012-00
2018	HIV RDT for self-testing	INSTI HIV Self Test	90-1071	RoW	biolytical Laboratories Inc.	Richmond, British Columbia, Canada	17/kit	https://extranet.who.int/prequal/WHOPR/public-report-insti-hiv-self-test-pqds-0002-002-01
2018	HIV RDT	One Step HIV1/2 Whole Blood/Serum/Plasma Test	W006-CAF2, W006-P0045, W006-P0046, W006-P0047, W006-P0048, W006-CAF2-F, W006-P0049, W006-P0050, W006-P0051, W006-P0052	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lohshan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	257/kit; 257/kit; 257/kit; 257/kit; 257/kit; 407/kit; 407/kit; 407/kit; 407/kit	https://extranet.who.int/prequal/WHOPR/public-report-one-step-hiv1-2-whole-blood-serum-plasma-test-pqds-0357-004-00

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2018	Malaria RDT	One Step test for Malaria Pf/Pv Ag MERSCREEN Malaria Pf/Pv Ag	MFLRFP-02; MFLRFP-03; MFLRFP-04; MFLRFP-05	CE-marked	Merit Diagnostics Pvt. Ltd.	D1-03, Merit Park, Survey No. 135/2/8 & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India	307/Nit; 257/Nit; 507/Nit; 107/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-one-step-test-malaria-pf-pv-ag-merscreen-malaria-pf-pv-ag-pdq-0794-074-00
2018	Malaria RDT	First Response Malaria Ag_pLDH/HRP2 Combo Card Test	P16FRFC10s; P16FRFC25s; P16FRFC25 P16FRFC30	RoW	Premier Medical Corporation Limited	site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; site 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Damam, Daman 396215, India	10 x single kit 25 x single kit 25 x multi kit 30 x multi kit	https://extranet.who.int/prequal/WHO/PR/public-report-first-response-malaria-ag-pldh/hrp2-combo-card-test-pdq-0285-010-00
2018	CD4 Technologies	Cyflow Counter System with CD4 easy count kit and CD4% easy count kit	CY-S-3023; OS-8401; and OS-8405	CE-marked	Sysmex Partec GmbH	site 1: Arndstr. 11a-b, 02826 G6rlitz, Germany; and site 2: Exbio Praha a.s., Nad Saffnou 8 341, 252 50 Vestec, Czech Republic	100 T/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-cyflow-counter-system-cd4-easy-count-kit-and-cd4-easy-count-kit-pdq-0350-081
2018	HPV Virological Technologies	care HPV Test	614015	CE-marked	QIAGEN GmbH	site 1: QIAGEN Sciences, Germantown, 20874, United States site 2: QIAGEN Shenzhen Co., Shenzhen China	96 T/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-carehpv-test-pdq-0085-028-00
2018	HCV EIA	INNOTEST HCV Ab IV	80306; 80330	CE-marked	Fujirebio Europe NV	Ghent, Belgium	1507/Nit 4807/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-innotest-hcv-ab-iv-pdq-0201-073-00
2017	HbAg RDT	Bioline HbAg WB	01FK10W	RoW	Abbott Diagnostics Korea Inc	Gheung-gu, Republic of Korea	307/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-bioline-hbaag-wb-pdq-0219-012-00
2017	HIV RDT	Genie Fast HIV 1/2	72337; 72347; 72330	CE-marked	Bio-Rad	Marne La Coquette, France	257/Nit; 507/Nit; 507/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-genie-fast-hiv-1-2-pdq-0153-031-00
2017	HPV Virological Technologies	Xpert HPV	GXHPV-CE-10	CE-marked	Cepheid AB	Solna, Sweden	107/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-xpert-hpv-pdq-0268-070-00-0
2017	HIV NAT	Aptima HIV 1 Quant Dx Assay	PRD-03000 (PRD-03002, PRD-03001); 303014; PRD-03003; and 303095	CE-marked	Hologic, Inc.	San Diego, USA	1007/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-aptima-hiv-1-quant-dx-assay-pdq-0236-078-00
2017	HIV RDT for self testing	OraQuick HIV Self Test	SK4-1000; SK4-1001; SK4-2001; Country specific variations are documented through a suffix "RST" to the product code on the outer packaging (i.e. SK4-1001.001, 002, ...).	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand	507/Nit; 2507/Nit; 1107/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-oraquick-hiv-self-test-pdq-0155-005-01
2017	HIV NAT	Xpert HIV-1 Viral Load	GXHV-VL-CE-10	CE-marked	Cepheid AB	Solna, Sweden	107/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-xpert-hiv-1-viral-load-geneamp-dx-geneamp-infinity-d8s-and-geneamp
2017	HCV NAT	Xpert HCV Viral Load	GXHCV-VL-CE-10	CE-marked	Cepheid AB	Solna, Sweden	107/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-xpert-hcv-viral-load-pdq-0260-070-00
2017	HIV Confirmatory Assay	Genieus HIV 1/2 Confirmatory Assay with Genieus HIV1/2 Confirmatory Controls	72460; and 72329	CE-marked	Bio-Rad	Marne-La-Coquette, France	207/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-genieus-hiv-1-2-confirmatory-assay-genieus-hiv-1-2-confirmatory-controls-pdq-0181
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1001-0270; 003-0274	CE-marked	OraSure Technologies, Inc.	Bethlehem, USA	257/Nit; 1007/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-oraquick-hiv-1-2-rapid-antibody-test-pdq-0159-055-00
2016	HIV RDT	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	R-401-SO-C-2; KH-R-02; and A-GOLD-01	RoW	Shanghai Kehua Bio-engineering Co., Ltd	Shanghai, PR China	507/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-diagnostic-kit-hiv-1-2-antibody-colloidal-gold-v2-pdq-0267-037-00
2016	HCV RDT	Bioline HCV	02FK10; 02FK16; 02FK17	RoW	Abbott Diagnostics Korea Inc	Gheung-gu, Republic of Korea	307/Nit; 257/Nit; 307/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-bioline-hcv-pdq-0217-012-00
2016	HIV RDT	Determine HIV Early Detect	702842; 702843; 70284387	RoW	Alere Medical Co. Ltd.	Matsudo-shi, Chiba-ken, Japan	207/Nit; 1007/Nit; 1007/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-determine-hiv-early-detect-pdq-0243-013-00
2016	HIV NAT	8 m PIMA HIV-1/2 Detect	2701R050 2703R001	CE-marked	Alere Technologies GmbH	lena, Germany	50 cartridges/Nit Instrument	https://extranet.who.int/prequal/WHO/PR/public-report-m-pima-hiv-1-2-detect-pdq-0276-032-00
2016	HIV RDT	DPP HIV 1/2 Assay	65-9506-0	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	207/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-dpp-hiv-1-2-assay-pdq-0013-006-00
2016	HIV RDT	OraQuick HIV 1/2 Rapid Antibody Test	SK4-0010; SK4-0014; SK4-0052; SK4-0012; SK4-0015	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand	1007/Nit; 1007/Nit; 1007/Nit; 5007/Nit; 5007/Nit	https://extranet.who.int/prequal/WHO/PR/public-report-oraquick-hiv-1-2-rapid-antibody-test-pdq-0159-055-00

WHO list of prequalified in vitro diagnostic products

 RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated
 Last update: 5 June 2024

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Application Number and Link to the Public Report
2016	HBsAg EIA	DS-EIA-HBsAg-Q01	8-1254/1.2; 8-1252/1.2; 8-1255/1.2; 8-1256/1.2; 8-231/1.2	CE-marked	RPC Diagnostics Systems	Nizhny Novgorod, Russia	967/kit; 1927/kit; 4807/kit; 967/kit (for detection) or 487/kit (for confirmation) 2007/kit	https://extranet.who.int/prequal/WHO/PR/public-report-ds-eia-hbsag-q01-enzyme-immunosay-detection-and-confirmation-9647014
2016	HIV Confirmatory Assay	MP Diagnostics HIV Blot 2.2	11030-Q18; 11030-Q36	CE-marked	MP Biomedicals Asia Pacific Pte Ltd.	Singapore, Singapore	187/kit; 367/kit	https://extranet.who.int/prequal/WHO/PR/public-report-mp-diagnostics-hiv-blot-22-pqdr-0198-071-00
2016	HIV EIA	AID anti-HIV 1+2 ELISA	W1-4396; W1-4348D	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	967/kit; 4807/kit	https://extranet.who.int/prequal/WHO/PR/public-report-aid-anti-hiv-1-2-eisa-pqdr-0006-005-00
2016	HIV RDT	Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	W1-185D; W1-185DE; W1-185O; W1-185OE; W1-185DEL; W1-185OEL; W1-185OEL; W1-18510; W1-18510L; W1-18510E; W1-18510E; W1-18510E; W1-18510E; W1-18510ELC; W1-18510ELC	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	107/kit; 107/kit; 507/kit; 507/kit; 107/kit; 507/kit; 107/kit; 107/kit; 507/kit; 107/kit; 507/kit; 107/kit; 507/kit; 107/kit; 507/kit	https://extranet.who.int/prequal/WHO/PR/public-report-rapid-test-antibody-human-immunodeficiency-virus-hiv-colloidal-gold-device-pqdr
2015	CD4 Technologies	Aquios CL flow cytometer	B20146; B23101; B23102; B25097; B25098; B23334; B23538; B23533; B23534; B23535; B25700; and B23502	CE-marked	Beckman Coulter Life Sciences	site 1: Miami, FL, USA (instrument site) site 2: Hialeah, FL, USA (reagent site)	507/kit	https://extranet.who.int/prequal/WHO/PR/public-report-aquios-cl-flow-cytometer-pqdr-0156-053-00
2015	HIV/Syph RDT	Bioline HIV/Syphilis Duo	06FK30; 06FK35; 06FK37	RoW	Abbott Diagnostics Korea Inc	Gyeongju, Republic of Korea	257/kit; 257/kit; 257/kit	https://extranet.who.int/prequal/WHO/PR/public-report-bioline-hiv-syphilis-duo-pqdr-0179-014-00
2015	Malaria RDT	Bioline Malaria Ag P.f./P.v	05FK8D; 05FK8L; 05FK8J; 05FK8I; 05FK8E; 05FK87	CE-marked	Abbott Diagnostics Korea Inc	Gyeongju, Republic of Korea	257/kit; 257/kit 17/kit x25 each 17/kit x25 each 107/kit 257/kit	https://extranet.who.int/prequal/WHO/PR/public-report-bioline-malaria-ag-pf-pv-pqdr-0125-012-00
2015	Malaria RDT	Bioline Malaria Ag P.f. (HRP2/pLDH)	05FK9D; 05FK9E; 05FK9I; 05FK9J	CE-marked	Abbott Diagnostics Korea Inc	Gyeongju, Republic of Korea	257/kit; 17/kit x25 each 257/kit 17/kit x 25 each	https://extranet.who.int/prequal/WHO/PR/public-report-bioline-malaria-ag-pf-hrp2-pqdr-0209-014-00
2015	HCV EIA	INNO-LIA HCV Score	80538	CE-marked	Fujirebio Europe NV	Zwijnaarde, Belgium	207/kit	https://extranet.who.int/prequal/WHO/PR/public-report-inno-lia-hcv-score-pqdr-0202-073-00
2015	HIV EIA	DS-EIA-HIV-AGAB-SCREEN	1-1654/1.2; 1-1652/1.2; 1-1656/1.2	CE-marked	RPC Diagnostics Systems	Nizhny Novgorod, Russia	967/ plate; 1927/7 plates; 480 175 plates	https://extranet.who.int/prequal/WHO/PR/public-report-ds-eia-hiv-agab-screen-pqdr-0106-038-00
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf/PAN) CDMBO	multi kit (product codes: RMRM-02571; RMRM-02571CB; RMRM-02571RB; RMRM-02571R); RMRM-05071; RMRM-05071CB; RMRM-05071RB and RMRM-05071R)	RoW	Access Bio, Inc.	Somerseset NJ, USA	257/kit; 507/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-hrp2-pldh-pf-pan-combo-pqdr-0136-049-00
2015	Malaria RDT	**CareStart Malaria HRP2 (Pf)	single kit (product codes: RMRU-02571; RMRU-02571CB; RMRU-02571RB; RMRU-02571R); RMRU-04071; RMRU-04071CB; RMRU-04071RB and RMRU-04071R)	RoW	Access Bio, Inc.	Somerseset NJ, USA	257/kit; 407/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-hrp2-pf-pqdr-0137-049-00
2015	Malaria RDT	**CareStart Malaria HRP2 (Pf)	multi kit (product codes: RMDM-02571; RMDM-02571CB; RMDM-02571RB; RMDM-02571R); RMDM-05071; RMDM-05071CB; RMDM-05071RB and RMDM-05071R)	RoW	Access Bio, Inc.	Somerseset NJ, USA	257/kit; 507/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-hrp2-pf-pqdr-0137-049-00
2015	Malaria RDT	**CareStart Malaria HRP2 (Pf)	single kit (product codes: RMDU-02571; RMDU-02571CB; RMDU-02571RB; RMDU-02571R); RMDU-05071; RMDU-05071CB; RMDU-05071RB and RMDU-05071R)	RoW	Access Bio, Inc.	Somerseset NJ, USA	257/kit; 407/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-hrp2-pf-pqdr-0137-049-00

WHO list of prequalified in vitro diagnostic products

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Last update: 5 June 2024

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Application Number and Link to the Public Report
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf/Pv) CD/MBD	<p>multi kit (product codes: RMVM-02571; RMVM-02571CB; RMFM-02571RB; RMVM-02571R; RMVM-05071; RMVM-05071CB; RMFM-05071RB and RMFM-05071R)</p> <p>single kit (product codes: RMVU-02571; RMVU-02571CB; RMVU-02571RB; RMVU-02571R; RMVU-05071; RMVU-05071CB; RMVU-05071RB and RMVU-05071R)</p>	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-hrp2pldh-pf-pv-combo-pqdr-0138-049-00
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf)	<p>multi kit (product codes: RMFM-02571; RMFM-02571CB; RMFM-02571RB; RMFM-02571R; RMFM-05071; RMFM-05071CB; RMFM-05071RB and RMFM-05071R)</p> <p>single kit (product codes: RMPU-02571; RMPU-02571CB; RMPU-02571RB; RMPU-02571R; RMPU-05071; RMPU-05071CB; RMPU-05071RB and RMPU-05071R)</p>	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-pf-hrp2pldh-pf-rdt-pqdr-0138-049-00
2015	Malaria RDT	**CareStart Malaria pLDH (PAN)	<p>multi kit (product codes: RMNM-02571; RMNM-02571CB; RMNM-02571RB; RMNM-02571R; RMNM-05071; RMNM-05071CB; RMNM-05071RB and RMNM-05071R)</p> <p>single kit (product codes: RMNU-02571; RMNU-02571CB; RMNU-02571RB; RMNU-02571R; RMNU-05071; RMNU-05071CB; RMNU-05071RB and RMNU-05071R)</p>	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-carestart-malaria-pan-pldh-pf-rdt-pqdr-0214-049-00
2015	HIV Confirmatory Assay	INNO-Lia HIV i/S Score	80540	CE-marked	Fujirebio Europe NV	Ghent, Belgium	20T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-inno-lia-hiv-i-score-pqdr-0203-073-00
2015	HIV EIA	Murex HIV Ag/Ab Combination	7679-09 (GE41, 96 wells); and 7679-11 (GE42, 480 wells)	CE-marked	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-murex-hiv-ag-ab-combination-pqdr-0164-049-00
2014	HIV NAT	COBAS Amplicor/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	06693083190; 03051315001; 0327832001; 03587797190; 06989861190; 05807875001; 03516440001; and 28127387001	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	48T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-amplicor-cobas-taqman-hiv-1-qualitative-test-v20-taqman-48-pqdr-0271
2014	HIV NAT	COBAS Amplicor/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	06693083190; 03587797190; 06989861190; 03051315001; 03121453001; 28127387001; 05807875001; and 03516440001	CE-marked	Roche Diagnostics GmbH	Mannheim, Germany	48T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-amplicor-cobas-taqman-hiv-1-qualitative-test-v20-taqman-96-pqdr-0200
2014	HIV RDT	SURE CHECK HIV 1/2 Assay	HIV201 (60 9527-0)	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	25T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-sure-check-hiv-1-2-assay-pqdr-0054-006-00
2014	HBsAg EIA	Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3	9F80-01; 9F80-05; 2627-01	CE-marked	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit; 50T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pqdr-0171-043-00
2014	Malaria RDT	ParahIT F Ver. 1.0 Rapid Test for P falciparum Malaria Device	55K104-10; 55K104-15; 55K104-50	CE-marked	ARKSAY Healthcare Pvt. Ltd.	Sachin (Surat), India	10T/kit; 25T/kit; 50T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-parahit-f-ver-1-0-rapid-test-p-falciparum-malaria-device-pqdr-0062-033-00
2014	CD4 Technologies	BD FACSPresto Near-Patient CD4 Counter with BD CD4KCD4/HS Cartridge and BD FACSPresto Cartridges kit	651000; 657681; 655495	CE-marked	Becton, Dickinson and Company, BD Biosciences	San Jose, California, USA	651000: instrument 657681: cartridge (100/box) 655495: pipette (100/box)	https://extranet.who.int/prequal/WHO/PR/public-report-bd-facspresto-near-patient-cd4-counter-system-pqdr-1197-044-00
2014	HIV RDT	ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IH-1402WI, IH-1402WA, IH-1402WG, IH-1402WB, IH-1402WD, IH-1402WE, IH-1402WF	RoW	ABON Biopharm (Hangzhou) Co. Ltd.	Hangzhou, PR China	40T/kit; 40T/kit; 40T/kit; 40T/kit; 10T/kit; 40T/kit; 10T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-abon-hiv-1-2-o-tri-line-human-immunodeficiency-virus-rapid-test-device-pqdr-0124
2013	HIV RDT	INSTI HIV-1/HIV-2 Antibody Test	90-1013; 90-1010; 90-1022; 90-1021; 90-1038; 90-1064	RoW	Biolytical Laboratories, Inc.	Richmond, British Columbia, Canada	24T/kit without support material; 24T/kit with support material; 48T/kit without support material; 48T/kit with support material; 48T/kit with pipettes but no lancet, no alcohol swabs); 48T/kit with no support material;	https://extranet.who.int/prequal/WHO/PR/public-report-insti-hiv-1-hiv-2-antibody-test-pqdr-0003-003-00
2013	Malaria RDT	BidiLine Malaria Ag P F/J/Pan	05FK60; 05FK61; 05FK62; 05FK63; 05FK67	CE-marked	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	25T/kit; 25x17/kit; 1T/kit; 25T/kit; 30T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-bidiline-malaria-ag-pf-jp-pan-pqdr-0130-012-01
2013	HIV NAT	Abbott RealTime HIV-1 Qualitative (Manual)	4N66-90; 4N66-80; 6K12-24; 9K15-01; 4N66-01; and 4N66-06 (optional)	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack	https://extranet.who.int/prequal/WHO/PR/public-report-abbott-realtime-hiv-1-qualitative-manual-pqdr-0141-012-00

WHO list of prequalified in vitro diagnostic products

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Last update: 5 June 2024

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Application Number and Link to the Public Report
2013	HIV NAT	Abbott RealTime HIV-1 Qualitative (m 2000sp)	4N66-90; 9K14-02; 9K15-01; 4N66-80; 4N66-01; 6K12-24; and 4N66-66 (optional)	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	967/kit; 4x24T pack	https://extranet.who.int/prequal/WHO/PR/public-report-abbott-realtime-hiv-1-qualitative-m2000sp-pqdr-0084-0377-00
2013	HIV RDT	Bioline HIV 1/2 3.0	03FK10; 03FK16; 03FK17	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	307/kit; 257/kit; 257/kit	https://extranet.who.int/prequal/WHO/PR/public-report-bioline-hiv-1-2-30-pqdr-0027-012-00
2013	HIV EIA	Genscreen ULTRA HIV Ag-Ab	72386; and 72388	CE-marked	Bio-Rad	Marnes La Coquette, France	967/kit; 4807/kit	https://extranet.who.int/prequal/WHO/PR/public-report-genscreen-ultra-hiv-ag-ab-pqdr-0094-031-00
2012	HIV RDT	Uni-Gold HIV	206502; 1206502N; 1206502E; 1206502M-100; 1206502-100; 1206502-C; 1206502-C; 1206502-C100	RoW	Trinity Biotech Manufacturing Ltd.	Bray, Ireland	207/kit; 207/kit; 1007/kit; 1007/kit; 207/kit; 207/kit; 1007/kit	https://extranet.who.int/prequal/WHO/PR/public-report-uni-gold-hiv-pqdr-0149-052-00
2012	CD4 Technologies	Pima CD4 Test	260100025 and 260300003; 260100100; and 260300003	CE-marked	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1, D-07743 Jena, Germany	25 cartridges/kit and instrument; 100 cartridges/kit and instrument	https://extranet.who.int/prequal/WHO/PR/public-report-pima-cd4-test-pqdr-0099-032-00
2012	CD4 Technologies	BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (Absolute CD4+, CD8+, and CD3+ Counts)	337858; 340166; 340167	CE-marked	Becton, Dickinson and Company, BD Biosciences	San Jose, CA, USA	337858: Instrument system 340166: 257/kit 340167: 507/kit	https://extranet.who.int/prequal/WHO/PR/public-report-bd-facscount-instrument-system-facscount-control-kit-and-bd-facscount-reagent
2012	CD4 Technologies	BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount CD4 Reagent Kit (Absolute and Percentage CD4+ Counts)	337858; 340166; 339010	CE-marked	Becton, Dickinson and Company, BD Biosciences	San Jose, CA, USA and Cary, Puerto Rico	337858: Instrument system 340166: 257/kit 339010: 507/kit	https://extranet.who.int/prequal/WHO/PR/public-report-bd-facscount-instrument-system-facscountm-control-kit-and-bd-facscountm-cd4
2012	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 48)	05212294190; 03587797190; 03121453001; 03051315001 or 05807875001 and 07963084190. Optional: 0527909001; 28127387001	CE-marked	Roche Diagnostics GmbH	Mannheim, Germany	05212294190: 48T/kit 03587797190: 5.1 liters	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-ampli-prep-cobas-taqman-hiv-1-test-version-20-taqman-48-pqdr-0126-036-00
2012	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 96)	05212294190; 03587797190; 03279322001; 03051315001; 07847308001 or 05807875001 and 07963084190. Optional: 0527909001; 28127387001	CE-marked	Roche Molecular Systems, Inc.	Branchburg, NJ, USA	05212294190: 48T/kit 03587797190: 5.1 liters	https://extranet.who.int/prequal/WHO/PR/public-report-cobas-ampli-prep-cobas-taqman-hiv-1-test-version-20-taqman-96-pqdr-0147-046-00
2012	HIV RDT	HIV 1/2 STAT-PAK	HIV101	RoW	Chembio Diagnostic Systems Inc.	Site 1: Chembio Diagnostic Systems, Inc. 13661 Horseshoe Road, Medford, Long Island, 11763, NY, USA Site 2: Chembio Diagnostics Malaysia Sdn. Bhd. located at N-TATT Building 2nd floor, No. 2-1 Jalan TPS, Taman Perindustrian, UEP, 47600, Subang Jaya, Selangor, Malaysia	207/kit	https://extranet.who.int/prequal/WHO/PR/public-report-hiv-1-2-stat-pak-pqdr-0007-006-00
2011	HIV NAT	NucliSENS EasyQ HIV-1 v2.0 (Automated)	280140; 280130; 280131; 280132; 280133; 280134; 285056; 200309; and 285033	CE-marked	bioMérieux SA	Marcy l'Etoile, France	280130; 280131; 280132; 280133 and 280134: 4x1L 285033: 48 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-nucli-sens-easyq-hiv-1-v2-0-automated-pqdr-0127-016-00
2011	HIV NAT	NucliSENS EasyQ HIV-1 v2.0 (Semi-Automated)	200305; 200293; 200292; 285056; 200309; and 285033	CE-marked	bioMérieux SA	Marcy l'Etoile, France	200293 and 200292: 48T/kit; 285033: 48 T/kit	https://extranet.who.int/prequal/WHO/PR/public-report-nucli-sens-easyq-hiv-1-v2-0-semi-automated-pqdr-0148-016-00-0
2011	HIV RDT	Determine HIV-1/2	702342; 702343; 702343SET and 702343SET5.	RoW	Abbott Diagnostics Medical Co., Ltd	Matsudo-shi, Chiba-ken, Japan	207/kit; 1007/kit; 1007/kit; 1007/kit	https://extranet.who.int/prequal/WHO/PR/public-report-determine-hiv-1-2-pqdr-0023-012-00
2011	HIV NAT	Abbott RealTime HIV-1 (Manual)	2G31 (2G31-90; 2G31-010; 2G31-80; 2G31-70); 2G31-66; 1168-09; 9K15-01; 04170-24; and 04170-93	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 967/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 month); 04170-24: 967/kit	https://extranet.who.int/prequal/WHO/PR/public-report-abbott-realtime-hiv-1-manual-pqdr-0146-021-00
2011	HIV NAT	Abbott RealTime HIV-1 (m 2000sp)	2G31 (2G31-90 or 2G31-010; 2G31-80; 2G31-70); 2G31-66; 1168-09; 9K15-01; 04170-24; 04171-93; and 9K14-02	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 967/kit (4x24T) or 2G31-010: 967/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 month); 04170-24: 967/kit	https://extranet.who.int/prequal/WHO/PR/public-report-abbott-realtime-hiv-1-m2000sp-pqdr-0145-022-00
2011	HIV NAT	Abbott RealTime HIV-1 (m 24sp)	3N06-01; 2G31(2G31-90; 2G31-80; 2G31-70); 2G31-66; 1168-09; 9K15-01; 04170-24; and 04171-93	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 967/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 month); 04170-24: 967/kit	https://extranet.who.int/prequal/WHO/PR/public-report-abbott-realtime-hiv-1-m24sp-pqdr-0083-0377-00

WHO list of prequalified in vitro diagnostic products

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 5 June 2024

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Application Number and Link to the Public Report
2010	Malaria RDT	Bioline Malaria Ag P.F	05FK50; 05FK51; 05FK52; 05FK53	CE-marked	Abbott Diagnostics Korea Inc	Gihungu-ku, Republic of Korea	257/Kit; 257/Kit; 17/Kit x 25 each; 17/Kit x 25 each.	http://extranet.who.int/prequal/WHOPR/public-consult/bioline-malaria-ag-pf-pdq-0031-012-01

** These products are subject to a WHO Notice of Concern: https://www.who.int/diagnostics_laboratory/procurement/complaints/en/.
The public reports were amended. Please view the public report to view the summary of the changes made on the public report and the product.

The following product will be discontinued by 31 July 2024:

 BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount CD4 Reagent Kit (Absolute and Percentage CD4+ Counts)
 BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (Absolute CD4+, CD8+, and CD3+ Counts)
 BD FACSPresto Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and BD FACSPresto Cartridges Kit

List of delisted Products

Year delisted	Type of assay	Product name	Product code(s)	Manufacturer	Reason for Delisting
2024	HIV Nucleic Acid Test	Xpert HIV-1 Qual Assay	GXRHV-QA-CE-10	Cepheid AB	Discontinuation of the product by the manufacturer.
2023	HIV Nucleic Acid Test	cobas HIV-1 Quantitative nucleic acid test for use on the cobas 4800 System	06979599190 and 06979572190	Roche Diagnostics GmbH	Discontinuation of the product by the manufacturer.
2023	HIV Nucleic Acid Test	m-PIMA HIV-1/2 Detect	27011-W50 and 27011R0310	Abbott Rapid Diagnostics Jena GmbH	Discontinuation of the RoW regulatory version. The CE-marked regulatory version maintained as prequalified.
2021	HIV RDT	HIV 1/ 2 STAT-PAK Dipstick	HIV903	ChemBio Diagnostic Systems, Inc.	Withdrawal by the manufacturer.
2021	HCV Assay	GeneDrive HCV ID Kit	ID-HCV-03	GeneDrive Diagnostics Ltd	Failure to verify the claimed analytical Limit of detection (LOD).
2021	HIV Serology	VIRIA HIV 1/2	31112	BioMérieux SA	Withdrawal by the manufacturer.
2021	HBSAg Assay	VIRIA HBSAg	31124	BioMérieux SA	Withdrawal by the manufacturer.
2020	HCV Assay	bioelsa HCV 4.0	3000-1115 and 3000	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV Serology	bioelsa HIV 1+2 Ag/Ab	3000-1172 and 3000-1173	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HBSAg Assay	bioelsa HBSAg 3.0	3000-1158 and 3000-1159	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV RDT	First Response HIV 1-2 Q Card test	05FRC100, 05FRC60, 05FRC30, and 05FRC05	Premier Medical Corporation Private Limited	Discontinuation of the product by the manufacturer.
2019	HCV Assay	Murex anti-HCV (version 4.0)	7751-01 and 7751-02	DiaSorin South Africa (Pty) Ltd.	Withdrawal by the manufacturer.
2019	HIV ELA	Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost/TMB	OPK8035, OPK8035, OPK8055(Q), and OLVN175	Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH
2019	HBSAg Assay	Enzygnost HBSAg 6.0 and Supplementary reagents kit for Enzygnost/TMB	OPH035 and OPH055	Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH
2018	HIV RDT	SD Bioline HIV Ag/Ab Combo	03FK30 and 03FK35	Abbott Diagnostics Korea Inc. (Formerly Standard Diagnostics, Inc.)	Discontinuation of the product by the manufacturer.
2017	Malaria RDT	ParahiT F Ver. 1.0 Rapid Test for P. Falciparum Malaria Dipstick	SSK103-10, SSK103-25 and SSK103-50	Ankay Healthcare Private Limited	Failure to meet product testing acceptance criteria.

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