

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: 30 July 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	Malaria RDT	Wondfo Malaria P.J (HRP2/αLDH) Test	W037P0022, W037P0028, W037P0030, W037P0024, W037P0033, W037P0035, and W037P0037.	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District Guangzhou, 510530, China	25 T/K 40 T/K 25 T/K 25 T/K 40 T/K 40 T/K 100 T/K	PQDx 0651-004-00(Public report to be published soon).
2024	HPV Virological Technologies	cobas 4800 HPV	05235804190, 05235762190, 05235910190, 05235901190, 05235855190, 05235839190, 05235812190, 05235871190, and 05235863190.	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	960 T/K 240 T/K 960 T/K 240 T/K 10 Sets 960 T/K 960 T/K 240 T/K	PQDx 0466-046-00 (Public report to be published soon).
2024	HIV NAT	Xpert HIV-1 Viral Load XC	GXHIV-VL-XC-CE-10	CE-marked	Cepheid AB	Cepheid AB located at Röntgenvägen 5 Solna, 17127, Sweden	10 T/kit	PQDx 0691-070-00 (Public Report to be published soon)
2024	HCV RDT for Self-Testing	OraQuick HCV Self-Test	3001-3217-###, 7x4-2001LJ-###, 7x4-1000-###, 7x4-1001-###, and 7x4-2001-### Country specific variations are documented through a suffix "###" to the product code on the outer packaging	CE-marked	OraSure Technologies, Inc.,	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand	Individual pouch for community and pharmacy distribution, Individual pharmacy unit box, 50 Count for community distribution, 200 Count for community distribution, 200 Count for pharmacy distribution.	PQDx 0244-055-01 (Public Report to be published soon)
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	PQDx 0640-027-00 (Public Report to be published soon)
2024	Malaria RDT	ONE STEP Malaria (Pf/Pv) Tri-line Test	ITPW11009-TC25, ITPW11009-TC40	RoW	InTec PRODUCTS, Inc	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	25 T/kit 40 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-one-step-malaria-pfpv-tri-line-test-pqdx-0627-017-00
2024	Malaria RDT	ONE STEP Malaria (Pf) Test	ITPW11007-TC25, ITPW11007-TC40	RoW	InTec PRODUCTS, Inc	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	25 T/kit 40 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-one-step-malaria-pf-test-pqdx-0626-017-00
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/WHOPR/public-report-xpert-hiv-1-qual-xc-pqdx-0652-070-00
2023	HCV RDT	First Response HCV Card Test	P03FRC25, P03FRC50, and P03FRC100	RoW	Premier Medical Corporation Private Limited	Premier Medical Corporation Ltd., at A1-302 and 3702 to 3705 and 3801 to 3805 WJ/2 and WJ/3, GIDC Sarigam 396155, Gujarat, India	25 T/kit, 50 T/kit, 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-first-response-hcv-card-test-pqdx-0469-010-00
2023	HIV NAT	cobas HIV-1/HIV-2 Qualitative nucleic acid test 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 06940528190	CE-marked	Roche Molecular Systems, Inc.,	Roche Molecular Systems, Inc., located at 1080 US Hwy 202 South Branchburg Township, 8879, United States of America	96 T/kit, 192 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-cobas-hiv-1hiv-2-pqdx-0528-046-00
2023	HCV RDT	HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma)	IHC-402WA, IHC-402WB, IHC-402WC, and IHC-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 40 T/kit 25 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-hcv-hepatitis-c-virus-rapid-test-device-whole-blood-serum-plasma-pqdx-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/WHOPR/public-report-samba-ii-hiv-1-qual-whole-blood-test-pqdx-0458-072-00
2023	HPV Virological Technologies	cobas HPV	07460155190, 07460171190, 07002238190, 06997546190, 06997511190, 06997538190, 06997503190	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	480 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-cobas-hpv-pqdx-0468-046-00

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: 30 July 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
2022	Syphilis RDT	Determine Syphilis TP	702452, 702453 and 702453SET	RoW	Abbott Diagnostics Medical Co., Ltd.	Abbott Diagnostics Medical Co., Ltd, located at 357 Matsuhida, Chiba-ken Matsudo-shi, 270-2214, Japan	30 T/kit 100 T/kit 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-determine-syphilis-tp-pqdx-0485-013-00
2022	HCV NAT	Xpert HCV VL Fingerstick	GXHCV-F5-CE-10	CE-marked	Cepheid AB	Röntngvägen 5, SE-171 54 Solna, Sweden	10 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-xpert-hcv-vl-fingerstick-pqdx-0453-070-00
2022	HIV RDT	Panbio HIV Verification Test	29011-W20 29011AW20	RoW	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1, Jena, Germany	20 T/kit 20 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-panbio-hiv-verification-test-pqdx-0480-032-00
2022	Malaria RDT	One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	RPWMPH-02, RPWMPH-03, RPWMPH-04	RoW	Meril Diagnostics Pvt. Ltd	Second Floor, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India	10 T/kit 25 T/kit 50 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-malaria-pf-hrp-ii-ag-pqdx-0470
2022	HIV NAT	cobas HIV-1 Nucleic acid test for use on the cobas 4800 System	08792902190, 06979572190,	CE-marked	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit; 10 sets;	https://extranet.who.int/prequal/WHOPR/public-report-cobas-hiv-1-nucleic-acid-test-use-cobas-4800-system-pqdx-0710-118-00
2022	HIV RDT for self-testing	Wondfo HIV Self-Test	W006P0058, W006P0059, and W006P0060	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	1 T/kit; 20 T/kit 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-wondfo-hiv-self-test-pqdx-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/WHOPR/public-report-checknow-hiv-self-test-pqdx-0481-032-00
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/WHOPR/public-report-trinscreen-hiv-pqdx-0473-052-00
2021	HCV NAT	cobas HCV (Quantitative nucleic acid test for use on cobas 5800/6800/8800 Systems)	6997732190 09040765190	CE-marked	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-hcv-cobas-PQdx-0465-046-00
2021	Syphilis RDT	First Response Syphilis Anti-TP Card Test	P108FRC25, P108FRC50 P108FRC100 P108FRC25-5A	RoW	Premier Medical Corporation Private 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 T/kit 50 T/kit 100 T/kit 25 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-first-response-syphilis-anti-tp-card-test-pqdx-0471-010-00
2020	HIV NAT	# cobas HIV-1 Quantitative nucleic acid test for use on the cobas 5800/6800/8800 Systems	07000995190 09040803190	CE-marked	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-580068008800-systems-pqdx
2020	HIV RDT	# MERISCREEN HIV 1-2 WB	HWWRPD-01 HWWRPD-02 HWWRPD-06 HWWRPD-07 HWWRPD-08 HWWRPD-09	CE-marked	Meril Diagnostics Pvt. Ltd.	Second Floor, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India	30 T/kit 40 T/kit 50 T/kit 10 T/kit 100 T/kit 100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-meriscreen-hiv-1-2-wb-pqdx-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	Onchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd	Plot nos. 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403722, India	1T/kit, 5T/kit 10 T/kit 25 T/kit 100 T/kit 25 x 1 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-paracheck-pf-rapid-test-pfalciparum-malaria-device-ver-3-pqdx-0321-024-00
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, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India	30 T/kit 10 T/kit 25 T/kit 50 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-one-step-test-malaria-pfpan-ag-meriscreen-malaria-pfpan-ag-pqdx-0330-074-00

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: 30 July 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
2020	CD4 Technologies	VISICT CD4 Advanced Disease	AB376	CE-marked	AccuBio Ltd	AccuBio Ltd located at Hillfoots Business, Village, Alva, FK12 5DQ United Kingdom.	25 T/kit	https://extranet.who.int/pqwweb/WHOPR/public-report-visitect-cd4-advanced-disease-pqdx-0384-077-00
2020	HIV RDT	STANDARD Q HIV 3/2 Ab 3-Line Test	09HV30D; 09HV30DM	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/pqwweb/WHOPR/public-report-standard-q-hiv-12-ab-3-line-test-pqdx-0383-117-00
2020	Malaria RDT	parascreen - Rapid test for Malaria Pan/Pf	503030025(1T) 503030010; 503030025; 503030050; 503030100	CE-marked	Zephyr Biomedicals – A Division of Tulip 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/pqwweb/WHOPR/public-report-parascreen-rapid-test-malaria-panpf-pqdx-0291-025-00
2020	Malaria RDT	FalciVax - Rapid test for Malaria Pv/Pf	503010025(1T) 503010010; 503010025; 503010050; 503010100	CE-marked	Zephyr Biomedicals – A Division of Tulip 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/pqwweb/WHOPR/public-report-falciVax-rapid-test-malaria-pv-pf-pqdx-0290-025-00
2020	HIV/Syp RDT	STANDARD Q HIV/Syphilis Combo Test	09HV20D	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/pqwweb/WHOPR/public-report-standard-q-hiv-syphilis-combo-test-pqdx-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 1.95 ml	https://extranet.who.int/prequal/WHOPR/public-report-ality-m-hcv-pqdx-0461-077-00
2020	Malaria RDT	STANDARD Q Malaria P f/P v Ag Test	09MAL20D	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/WHOPR/public-report-standard-q-malaria-pfv-ag-test-pqdx-0348-117-00
2020	Malaria RDT	STANDARD Q Malaria P f Pan Ag Test	09MAL30D	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/WHOPR/public-report-standard-q-malaria-pfpan-ag-test-pqdx-0347-117-00
2020	Malaria RDT	STANDARD Q Malaria P f Ag Test	09MAL10D	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/WHOPR/public-report-standard-q-malaria-pf-ag-test-pqdx-0346-117-00
2020	HCV RDT	STANDARD Q HCV Ab Test	09HCV10D	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/WHOPR/public-report-standard-q-hcv-ab-test-pqdx-0360-117-00
2020	HCV EIA	Monolisa HCV Ag-Ab ULTRA V2	72561 and 72562	CE-marked	Bio-Rad	3, bd Raymond Poincaré, 92430, Marne La Coquette, France and Route de Cassel, 59114, Steenvoorde, France	96 T/kit 480 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-monolisa-hcv-ag-ab-ultra-v2-pqdx-0229-031-00
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/WHOPR/public-report-abbott-realttime-hcv-pqdx-0450-077-00
2019	HIV RDT for self-testing	SURE CHECK HIV Self-Test	60-9508-0	RoW	ChemBio Diagnostic Systems, Inc	3651 Horseblock Road, Medford, NY 11763 USA	1 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-sure-check-hiv-self-test-pqdx-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/WHOPR/public-report-abbott-realttime-high-risk-hpv-pqdx-0455-180-00

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: 30 July 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
2019	HIV RDT	First Response HIV 1-2.0 Card test (Version 2.0)	P105FK05; P105FK10; P105FK25; P105FK30; P105FK50; P105FK60	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	https://extranet.who.int/prequal/WHOPR/public-report-first-response-hiv-1-2o-card-test-pdx-0363-010-00
2019	HBsAg RDT	Determine HBsAg 2	7D2942; 7D2943; 7D2943 SET	RoW	Abbott Diagnostics Medical Co.Ltd	357 Matsuhida, 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-pdx-0451-013-00
2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02; and 8C89-01	CE-marked	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, Japan	100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-architect-hcv-ag-assay-pdx-0374-130-00
2019	HIV RDT for self-testing	Mylan HIV Self Test	ARST001-03; ARST001-03-01; ARST001-03-02; ARST005-03-03	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, Muisenberg 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-pdx-0320-090-00
2019	HIV/Syp RDT	First Response HIV1+2/Syphilis Combo Card Test	I20FR25; I20FR30; I20FR50; I20FR60; 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-responser-hiv12syphilis-combo-card-test-pdx-0364-010-00
2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40 ITPW02152-TC25 ITPW02153-TC40 ITPW02153-TC40SA ITPW02154-TC40	RoW	inTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361002, 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-12-test-pdx-0372-017-00
2019	HCV RDT	Rapid Anti-HCV Test	ITPW01152-TC40; ITPW01152-TC25; ITPW01153-TC40	RoW	inTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361002, China	40 T/kit 25 T/kit 40 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-rapid-anti-hcv-test-pdx-0371-017-00
2019	Malaria RDT	AdvDx Malaria Pf Rapid Malaria Ag Detection Test	00-DKM-RK-MAL-ADX-004-001, 00-DKM-RK-MAL-ADX-004-025, 00-DKM-RK-MAL-ADX-004-010, and 00-DKM-RK-MAL-ADX-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-advd-malaria-pf-rapid-malaria-ag-detection-test-pdx-0345-101-00
2019	Malaria RDT	NxTek Eliminate Malaria Pf and and NxTek Malaria Pf	05FK140; 05FK141; 05FK142; 05FK143	CE-marked	Abbott Diagnostics Korea Inc	Site 1: 46, Hagar-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea Site 2: 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	25T/kit; 25T/kit; 1T/kit x 25 each; 1T/kit x 25 each	https://extranet.who.int/prequal/WHOPR/public-report-netek-eliminate-malaria-pf-pdx-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-12-vl-pdx-0359-032-00
2018	Malaria RDT	First Response Malaria Antigen P. falciparum (HRP2) Card Test	P113FR25a; P113FR10a; P113FR25; P113FR30;	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-responser-malaria-antigen-p-falciparum-hrp2-card-test-pdx-0283-010-00
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	P119FR10a; P119FR25a; P119FR30; P119FR25	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-responsermalaria-ag-pf-pv-card-test-pdx-0329-010-00
2018	Malaria RDT	Bioline Malaria Ag P.f/P.v	05FK120; 05FK123	CE-marked	Abbott Diagnostics Korea Inc	65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea	25T/kit; 1T/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-malaria-ag-pf/pv-pdx-0287-012-00
2018	HIV RDT for self-testing	INSTI HIV Self Test	90-1071	RoW	bioLytical Laboratories Inc.	Richmond, British Columbia, Canada	1T/kit	https://extranet.who.int/prequal/WHOPR/public-report-insti-hiv-self-test-pdx-0002-002-01
2018	HIV RDT	One Step HIV1/2 Whole Blood/Serum/Plasma Test	W006-C4P2; W006-P0045; W006-P0046; W006-P0047	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lishihan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	25T/kit; 25T/kit; 25T/kit; 25T/kit;	https://extranet.who.int/prequal/WHOPR/public-report-one-step-hiv12-whole-bloodserumplasma-test-pdx-0357-004-00

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: 30 July 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
2018	Malaria RDT	One Step test for Malaria Pf/Pv Ag MERSCREEN Malaria Pf/Pv Ag	MFLRPD-02; MFLRPD-03; MFLRPD-04; MFLRPD-05	CE-marked	Meril Diagnostics Pvt. Ltd.	D1-03, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396199, Gujarat, India	307/kit; 257/kit; 507/kit; 10 T/kit.	https://extranet.who.int/prequal/WHOPR/public-report-one-step-test-malaria-pf-pv-ag-merscreen-malaria-pf-pv-ag-pgdx-0794-074-00
2018	Malaria RDT	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	P116FRC10s P116FRC25s P116FRC25 P116FRC30	RoW	Premier Medical Corporation Limited	site 1: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; site 2: 32-35A, Shree Ganesh Industrial Estate, Kachhram, Raji/Daman, Daman 396215, India	10 × single kit 25 × single kit 25 × multi kit 30 × multi kit	https://extranet.who.int/prequal/WHOPR/public-report-first-responder-malaria-ag-pldhhrp2-combo-card-test-pgdx-0385-010-00
2018	CD4 Technologies	CyFlow Counter System with CD4 easy count kit and CD4% easy count kit	CY-S-3023; 05-8401; and 05-8405	CE-marked	Sysmex Partec GmbH	site 1: Arndtsstr. 13a b, 02826 Görlitz, Germany; and site 2: Šabůvka Praha a.s., Nad Šabůvkou II 341, 252 50 Vestec, Czech Republic	100 T/kit	https://extranet.who.int/prequal/WHOPR/public-report-cyflow-counter-system-cd4-easy-count-kit-and-cd4-easy-count-kit-pgdx-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/kit	https://extranet.who.int/prequal/WHOPR/public-report-carehpv-test-pgdx-0085-028-00
2018	HCV EIA	INNOTEST HCV Ab IV	80068; 80330	CE-marked	Fujirebio Europe NV	Ghent, Belgium	1927/kit 4807/kit	https://extranet.who.int/prequal/WHOPR/public-report-innotest-hcv-ab-iv-pgdx-0201-073-00
2017	HBsAg RDT	Bioline HBsAg WB	01FK10W	RoW	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	307/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-hbsag-wb-pgdx-0219-012-00
2017	HIV RDT	Genie Fast HIV 1/2	72327; 72347; 72330	CE-marked	Bio-Rad	Marne La Coquette, France	257/kit 507/kit 507/kit	https://extranet.who.int/prequal/WHOPR/public-report-genie-fast-hiv-1-2-pgdx-0153-031-00
2017	HPV Virological Technologies	Xpert HPV	GXHPV-CE-10	CE-marked	Cepheid AB	Solna, Sweden	107/kit	https://extranet.who.int/prequal/WHOPR/public-report-xpert-hpv-pgdx-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/kit	https://extranet.who.int/prequal/WHOPR/public-report-aptima-hiv-1-quant-dx-assay-pgdx-0236-078-00
2017	HIV RDT for self-testing	OraQuick HIV Self-Test	5X4-1000; 5X4-1001; 5X4-2001; Country specific variations are documented through a suffix "##F" to the product code on the outer packaging (i.e. 5X4-1001.001, 002, ...)	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand	507/kit; 2507/kit; 1107/kit	https://extranet.who.int/prequal/WHOPR/public-report-oraquick-hiv-self-test-pgdx-0159-055-01
2017	HIV NAT	Xpert HIV-1 Viral Load	GXHIV-VL-CE-10	CE-marked	Cepheid AB	Solna, Sweden	107/kit	https://extranet.who.int/prequal/WHOPR/public-report-xpert-hiv-1-viral-load-geneexpert-dx-geneexpert-infinity-58s-end-geneexpert
2017	HCV NAT	Xpert HCV Viral Load	GXHCV-VL-CE-10	CE-marked	Cepheid AB	Solna, Sweden	107/kit	https://extranet.who.int/prequal/WHOPR/public-report-xpert-hcv-viral-load-pgdx-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	Marnes-La-Coquette, France	207/kit	https://extranet.who.int/prequal/WHOPR/public-report-genieus-hiv-1-2-confirmatory-assay-genieus-hiv1-2-confirmatory-controls-pgdx-0181
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1001-0270; 001-0274	CE-marked	OraSure Technologies, Inc.	Bethlehem, USA	257/kit; 1007/kit	https://extranet.who.int/prequal/WHOPR/public-report-oraquick-hiv-12-rapid-antibody-test-pgdx-0159-055-00
2016	HIV RDT	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	R-401-50-C-2; KH-R-02; and A-GOLD-01	RoW	Shanghai Kehua Bio-engineering Co., Ltd	Shanghai, PR China	507/kit	https://extranet.who.int/prequal/WHOPR/public-report-diagnostic-kit-hiv12-antibody-colloidal-gold-v2-pgdx-0262-037-00
2016	HCV RDT	Bioline HCV	02FK10; 02FK16; 02FK17	RoW	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	307/kit 257/kit 307/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-hcv-pgdx-0257-012-00
2016	HIV RDT	Determine HIV Early Detect	702842; 702843; 702843SET	RoW	Alere Medical Co. Ltd.	Matsudo-shi, Chiba-ken, Japan	207/kit; 1007/kit; 1007/kit	https://extranet.who.int/prequal/WHOPR/public-report-determine-hiv-early-detect-pgdx-0243-013-00

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: 30 July 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	HIV NAT	# m-PIMA HIV-1/2 Detect	2701R050 27030R001	CE-marked	Alera Technologies GmbH	Jena, Germany	50 cartridges/kit Instrument	https://extranet.who.int/prequal/WHOPR/public-report-m-pima-hiv-12-detect-pqdx-0226-032-00
2016	HIV RDT	DPP HIV 1/2 Assay	65-9506-0	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	20T/kit	https://extranet.who.int/prequal/WHOPR/public-report-dpp-hiv-12-assay-pqdx-0053-006-00
2016	HIV RDT	OraQuick HIV 1/2 Rapid Antibody Test	5x4-0010; 5x4-0014; 5x4-0062; 5x-0012; 5x-0015	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Petchabun, Thailand site 3: Ayutthaya, Thailand	100T/kit; 100T/kit; 100T/kit 500T/kit 500T/kit	https://extranet.who.int/prequal/WHOPR/public-report-oraquick-hiv-12-rapid-antibody-test-pqdx-0159-055-00
2016	HBSAg EIA	DS-EIA-HBSAg-0,01	B-1254/1,2; B-1252/1,2; B-1256/1,2; B-1256/1,2; B-233/1,2	CE-marked	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/kit; 192T/kit; 480T/kit; 96T/kit (for detection) or 48T/kit (for confirmation) 200T/kit	https://extranet.who.int/prequal/WHOPR/public-report-ds-eia-hbsag-001-enzyme-immunoassay-detection-and-confirmation-hepatitis-b
2016	HIV Confirmatory Assay	MP Diagnostics HIV Blot 2.2	11030-018; 11030-036	CE-marked	MP Biomedicals Asia Pacific Pte.Ltd.	Singapore, Singapore	18T/kit; 36T/kit	https://extranet.who.int/prequal/WHOPR/public-report-mp-diagnostics-hiv-blot-22-pqdx-0198-071-00
2016	HIV EIA	AID anti-HIV 1+2 ELISA	WI-4396; WI-43480	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	96T/kit; 480T/kit	https://extranet.who.int/prequal/WHOPR/public-report-aid-anti-hiv-12-elisa-pqdx-0306-005-00
2016	HIV RDT	Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	WI-1810; WI-1810E; WI-1850; WI-1850E; WI-1810E1; WI-1810E1; WI-1850E1;	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	10T/kit 10T/kit; 50T/kit; 50T/kit; 10 T/kit; 50 T/kit;	https://extranet.who.int/prequal/WHOPR/public-report-rapid-test-antibody-human-immunodeficiency-virus-hiv-colloidal-gold-device-pqdx
2015	CD4 Technologies	Aquios CL flow cytometer	830166; 839101; 839102; 825697; 825698; 823536; 823538; 823533; 823534; 823535; 825700; and 823502	CE-marked	Beckman Coulter Life Sciences	site 1: Miami, FL, USA (instrument site) site 2: Hialeah, FL, USA (reagent site)	50T/kit	https://extranet.who.int/prequal/WHOPR/public-report-aquios-cl-flow-cytometer-pqdx-0156-053-00
2015	HIV/Syph RDT	Bioline HIV/Syphilis Duo	06FK30; 06FK35; 06FK37	RoW	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	25T/kit; 25T/kit; 25T/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-hiv-syphilis-duo-pqdx-0179-012-00
2015	Malaria RDT	Bioline Malaria Ag P.f/P.v	05FK80; 05FK81; 05FK82; 05FK83; 05FK86;	CE-marked	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	25T/kit; 25T/kit 1T/kit x25 each 1T/kit x25 each 10T/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-malaria-ag-pf-pv-pqdx-0125-012-00
2015	Malaria RDT	Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90; 05FKPK93; 05FK91; 05FK092	CE-marked	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	25T/kit; 1T/kit x25 each 25T/kit 1T/kit x 25 each	https://extranet.who.int/prequal/WHOPR/public-report-bioline-malaria-ag-pf-hrp2-pldh-pqdx-0209-012-00

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: 30 July 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	HCV EIA	INNO-LiA HCV Score	80538	CE-marked	Fujirebio Europe NV	Zwijnaarde, Belgium	20T/kit	https://extranet.who.int/prequal/WHOPR/public-report-ino-li-hcv-score-pqdx-0202-073-00
2015	HIV EIA	DS-EIA-HIV-AGAB-SCREEN	I-1654/1,2; I-1652/1,2; I-1656/1,2	CE-marked	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/1 plate; 15372 plates; 480 T/S plates	https://extranet.who.int/prequal/WHOPR/public-report-ds-hiv-agab-screen-pqdx-0106-038-00
2015	HIV Confirmatory Assay	INNO-LiA HIV I/II Score	80540	CE-marked	Fujirebio Europe NV	Ghent, Belgium	20T/kit	https://extranet.who.int/prequal/WHOPR/public-report-ino-li-hiv-ii-score-pqdx-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/WHOPR/public-report-murex-hiv-ag-ab-combination-pqdx-0144-043-00
2014	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	06693083190; 03051315001; 03279222001; 03587797190; 06989861190; 05807875001; 03516440001; and 28127387001	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	48T/kit	https://extranet.who.int/prequal/WHOPR/public-report-cobas-ampli-prep-cobas-taqman-hiv-1-qualitative-test-v20-taqman-48-pqdx-0221
2014	HIV NAT	COBAS AmpliPrep/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/WHOPR/public-report-cobas-ampli-prep-cobas-taqman-hiv-1-qualitative-test-v20-taqman-96-pqdx-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/WHOPR/public-report-sure-check-hiv-1-2-assay-pqdx-0064-006-00
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/WHOPR/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pqdx-0121-043-00
2014	Malaria RDT	ParahiT F Ver. 1.0 Rapid Test for P.falciparum Malaria Device	55C104-10; 55C104-25; 55C104-50	CE-marked	ARKRAY Healthcare Pvt. Ltd.	Sachin (Surat), India	10T/kit; 25T/kit; 50T/kit	https://extranet.who.int/prequal/WHOPR/public-report-parahit-f-ver-1-0-rapid-test-p-falciparum-malaria-device-pqdx-0063-023-00
2014	CD4 Technologies	BD FACSPresto Near-Patient CD4 Counter with BD CD4KCD4/Hb 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/WHOPR/public-report-bd-facspresto-near-patient-cd4-counter-system-pqdx-0192-045-00
2014	HIV RDT	ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IH-T402WI, IH-T402WA, IH-T402WO, IH-T402WB, IH-T402WD, IH-T402WE, IH-T402WF	RoW	ABON Biopharm (Hangzhou) Co. Ltd.	Hangzhou, PR China	40T/kit; 40T/kit; 40T/kit; 10T/kit; 40T/kit; 10T/kit	https://extranet.who.int/prequal/WHOPR/public-report-abon-hiv-1-2-o-tri-line-human-immunodeficiency-virus-rapid-test-device-pqdx-0141
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/WHOPR/public-report-insti-hiv-1-hiv-2-antibody-test-pqdx-0002-002-00
2013	Malaria RDT	Bioline Malaria Ag P./Pan	05FK60; 05FK61; 05FK62; 05FK63; 05FK67	CE-marked	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	25T/kit; 25x3T/kit; 1T/kit; 25T/kit; 30T/kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-malaria-ag-p/pan-pqdx-0030-012-01

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: 30 July 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 (Manual)	4N66-90; 4N66-80; 6K12-24; 9K15-01; 4N66-01; and 4N66-66 (optional)	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	967 /kit; 4x24T pack	https://extranet.who.int/prequal/WHOPR/public-report-abbott-realtime-hiv-1-qualitative-manual-pqdx-0151-027-00
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/WHOPR/public-report-abbott-realtime-hiv-1-qualitative-m2000sp-pqdx-0084-027-00
2013	HIV RDT	BioLine HIV-1/2 3.0	03FK10; 03FK16; 03FK17	RoW	Abbott Diagnostics Korea Inc	Gyeong-gu, Republic of Korea	307 /kit; 257 /kit; 257 /kit	https://extranet.who.int/prequal/WHOPR/public-report-bioline-hiv-1-2-30-pqdx-0027-912-00
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/WHOPR/public-report-genscreen-ultra-hiv-ag-ab-pqdx-0096-031-00
2012	HIV RDT	Uni-Gold HIV	206502; 1206502N; 1206502K; 1206502N-100; 1206502-100; 1206502-C; 1206502E-C; 1206502-C100	RoW	Trinity Biotech Manufacturing Ltd.	Bray, Ireland	207 /kit; 207 /kit; 207 /kit; 1007 /kit; 1007 /kit; 207 /kit; 207 /kit; 1007 /kit	https://extranet.who.int/prequal/WHOPR/public-report-uni-gold-hiv-pqdx-0149-052-00
2012	CD4 Technologies	Pima CD4 Test	260100025 and 260300003; 260100100; and 260300003	CE-marked	Abbott Rapid Diagnostics Jena GmbH	Orlweg 1, D-07743 Jena, Germany	25 cartridges/kit and instrument; 100 cartridges/kit and instrument	https://extranet.who.int/prequal/WHOPR/public-report-pima-cd4-test-pqdx-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: 25T /kit 340167: 50T /kit	https://extranet.who.int/prequal/WHOPR/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 Cayey, Puerto Rico	337858: instrument system 340166: 25T /kit 339010: 50T /kit	https://extranet.who.int/prequal/WHOPR/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: 05527503001; 28127387001	CE-marked	Roche Diagnostics GmbH	Mannheim, Germany	05212294190: 48T/kit 03587797190: 5.1 liters	https://extranet.who.int/prequal/WHOPR/public-report-cobas-ampli-prep-cobas-taqman-hiv-1-test-version-20-isomn-48-pqdx-0126-046-00
2012	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 96)	05212294190; 03587797190; 03279332001; 03051315001; 07347308001 or 05807875001 and 07963084190. Optional: 05527503001; 28127387001	CE-marked	Roche Molecular Systems, Inc.	Branchburg, NJ, USA	05212294190: 48T/kit 03587797190: 5.1 liters	https://extranet.who.int/prequal/WHOPR/public-report-cobas-ampli-prep-cobas-taqman-hiv-1-test-version-20-isomn-96-pqdx-0147-046-00
2012	HIV RDT	HIV 1/2 STAT-PAK	HIV101	RoW	Chembio Diagnostic Systems Inc.	Site 1: Chembio Diagnostic Systems, Inc. 13661 Horseblock 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	20T /kit	https://extranet.who.int/prequal/WHOPR/public-report-hiv-1-2-stat-pak-pqdx-0007-006-00
2011	HIV RDT	Determine HIV-1/2	702342; 702343; 702343SET and 702343SET5.	RoW	Abbott Diagnostics Medical Co., Ltd	Matsudo-shi, Chiba-ken, Japan	20T /kit; 100T /kit; 100T /kit; 100T /kit	https://extranet.who.int/prequal/WHOPR/public-report-determine-hiv-1-2-pqdx-0033-013-00
2011	HIV NAT	Abbott RealTime HIV-1 (Manual)	2G31 (2G31-90, 2G31-80, 2G31-70); 2G31-66; 1168-09; 9K15-01; 0470-24; and 0471-93	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 months); 0470-24: 967 /kit	https://extranet.who.int/prequal/WHOPR/public-report-abbott-realtime-hiv-1-manual-pqdx-0146-027-00
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; 0470-24; 0471-93; 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 months); 0470-24: 967 /kit	https://extranet.who.int/prequal/WHOPR/public-report-abbott-realtime-hiv-1-m2000sp-pqdx-0145-027-00



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: 30 July 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
2011	HIV NAT	Abbott RealTime HIV-1 (m 24sp)	3N06-01, 2G31(2G31-90, 2G31-80, 2G31-70); 2G31-66; 1168-05; 9A15-01; 04/70-24; and 04/71-93	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04/70-24: 96T/kit	https://extranet.who.int/prequal/WHOPR/public-report-abbott-realtime-hiv-1-m24sp-pdx-0083-027-00
2010	Malaria RDT	Bioline Malaria Ag P.f	05FK50; 05FK51; 05FK52; 05FK53	CE-marked	Abbott Diagnostics Korea Inc	Gihung-ku, Republic of Korea	25T/kit; 17/kit x 25 each; 17/kit x 25 each.	https://extranet.who.int/prequal/WHOPR/public-report-bioline-malaria-ag-pf-pdx-0031-012-01

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	NuclISENS EasyQ HIV-1 v2.0 (Semi-Automated)	200305, 200293, 200292, 285056, 200309 and 285033	BioMérieux S.A	Discontinuation of the product by the manufacturer.
2024	HIV Nucleic Acid Test	NuclISENS EasyQ HIV-1 v2.0 (Automated)	4700014, 280130, 280131, 280132, 280133, 280134, 285056, 4700016, and 285033	BioMérieux S.A	Discontinuation of the product by the manufacturer.
2024	Malaria RDT	CareStart Malaria HRP2/pLDH (Pf/PAN) COMBO	multi kit (product codes: RMMM-02571; RMMM-02571CB; RMM-02571RB; RMM-02571R; RMM-05071; RMM-05071CB; RMM-05071RB and RMM-05071R)	Access Bio, Inc.	Failure of Access Bio, Inc.'s manufacturing site to comply with WHO standards (ISO13485:2016)
2024	Malaria RDT	CareStart Malaria HRP2 (Pf)	multi kit (product codes: RMOM-02571; RMOM-02571CB; RMOM-02571RB; RMOM-02571R; RMOM-05071; RMOM-05071CB; RMOM-05071RB and RMOM-05071R)	Access Bio, Inc.	Failure of Access Bio, Inc.'s manufacturing site to comply with WHO standards (ISO13485:2016)
2024	Malaria RDT	CareStart Malaria HRP2/pLDH (Pf/Pv) COMBO	multi kit (product codes: RMVM-02571; RMVM-02571CB; RMVM-02571RB; RMVM-02571R; RMVM-05071; RMVM-05071CB; RMVM-05071RB and RMVM-05071R)	Access Bio, Inc.	Failure of Access Bio, Inc.'s manufacturing site to comply with WHO standards (ISO13485:2016)
2024	Malaria RDT	CareStart Malaria HRP2/pLDH (Pf) (PF)	multi kit (product codes: RMPM-02571; RMPM-02571CB; RMPM-02571RB; RMPM-02571R; RMPM-05071; RMPM-05071CB; RMPM-05071RB and RMPM-05071R)	Access Bio, Inc.	Failure of Access Bio, Inc.'s manufacturing site to comply with WHO standards (ISO13485:2016)
2024	Malaria RDT	CareStart Malaria pLDH (PAN)	multi kit (product codes: RMNM-02571; RMNM-02571CB; RMNM-02571RB; RMNM-02571R; RMNM-05071; RMNM-05071CB; RMNM-05071RB and RMNM-05071R)	Access Bio, Inc.	Failure of Access Bio, Inc.'s manufacturing site to comply with WHO standards (ISO13485:2016)
2024	HIV Nucleic Acid Test	Xpert HIV-1 Qual Assay	GXHIV-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 27011R010	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	HIV303	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	VIKIA HIV 1/2	31112	BioMérieux SA	Withdrawal by the manufacturer.
2021	HbAg Assay	VIKIA HbSAg	31124	BioMérieux SA	Withdrawal by the manufacturer.
2020	HCV Assay	bioelisa HCV 4.0	3000-1115 and 3000	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV Serology	bioelisa HIV 1+2 Ag/Ab	3000-1172 and 3000-1173	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HbAg Assay	bioelisa HbSAg 3.0	3000-1158 and 3000-1159	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV RDT	First Response HIV 1-2-0 Card test	105FRC100, 105FRC30, 105FRC30, and 105FRC05	Premier Medical Corporation Private Limited	Discontinuation of the product by the manufacturer.
2019	HCV Assay	Murex anti-HCV (version 4.0)	7F51-01 and 7F51-02	DiaSorin South Africa (Pty) Ltd.	Withdrawal by the manufacturer.
2019	HIV EIA	Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost/TMB	OPKR035, OPKR035, OPKR055(Q), and OUVV175	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 Ver. 1.0 Rapid Test for P. Falciparum Malaria Dipstick	55IC103-10, 55IC103-25 and 55IC103-50	Arkay Healthcare Private Limited	Failure to meet product testing acceptance criteria.

End of document