

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: 19 April 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	Xpert HIV-1 Qual KC	G0HIV-QA-KC-CE-10	CE-marked	Cepheid AB	Cepheid AB located at Rönngenvägen 5 Solna, 17127, Sweden	10 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-xpert-hiv-1-qual-kc-page-0463-070-00
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 W/2 and W/3, GIDC Sarigam 396355, Gujarat, India	25 T/kit, 50 T/kit, 100 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-first-response-hcv-card-test-page-0469-070-00
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 05060238100	CE-marked	Roche Molecular Systems, Inc.,	Roche Molecular Systems, Inc., located at 3080 US Hwy 202 South Branchburg Township, 8879, United States of America	96 T/kit, 192 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-cobas-hiv-1-hiv-2-qna-page-0468-046-00
2023	HCV RDT	HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma)	HC-4026A, HC-4026B, HC-4026C, and HC-4026D	RoW	ABON Biopharm (Hangzhou) CO., LTD	Abon Biopharm (Hangzhou) CO., LTD, located 138# 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/WHOQPP/public-report-hcv-hepatitis-c-virus-rapid-test-device-whole-blood-serum-plasma-page-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/WHOQPP/public-report-samba-ii-hiv-1-qual-whole-blood-test-page-0453-071-00
2023	HPV Virological Technologies	cobas HPV	07460155190, 07460171190, 07002238190, 06997548190, 06997511190, 06997538190, 06997503190	CE-marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	480 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-cobas-hpv-page-0466-046-00
2022	Syphilis RDT	Determine Syphilis TP	703452, 703453 and 703453&T	RoW	Abbott Diagnostics Medical Co., Ltd.	Matsuhida, Chiba-ken Matsudo-shi, 270-2214, Japan	30 T/kit, 100 T/kit, 100 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-determine-syphilis-tp-page-0465-013-00
2022	HCV NAT	Xpert HCV VL Fingertick	G0HCV-FS-CE-10	CE-marked	Cepheid AB	Rönngenvägen 5, SE-171 54 Solna, Sweden	10 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-xpert-hcv-vl-fingertick-page-0453-070-00
2022	HIV RDT	Parbio HIV Verification Test	29011-WO20 29011-AW20	RoW	Abbott Rapid Diagnostics Jena GmbH	Ortsweg 1, Jena, Germany	20 T/kit, 20 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-parbio-hiv-verification-test-page-0480-032-00
2022	Malaria RDT	One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	SPWAMPH-02, SPWAMPH-03, SPWAMPH-04	RoW	Merit Diagnostics Pvt. Ltd.	Second Floor, D1-03, Merit Park, Survey No 135/2/B & 174/2, Mukundan Marg, Chola, Vapi, 396191, India	10 T/kit, 25 T/kit, 50 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-malaria-pf-hrp-ii-ag-page-0470
2022	HIV NAT	cobas HIV-1 Nucleic acid test for use on the cobas 4800 System	08792992190, 080795712190	CE-marked	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit, 10 Sets	https://extranet.who.int/prequal/WHOQPP/public-report-cobas-hiv-1-nucleic-acid-test-use-cobas-4800-systems-page-0710-118-00
2022	HIV RDT for self-testing	Wondfo HIV Self-Test	W00GP0058, W00GP0059, and W00GP0060	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lufshan Road, Science City, Longgang District, Guangzhou, 510661, Republic of China	1 T/kit, 20 T/kit, 100 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-wondfo-hiv-self-test-page-0307-004-00
2022	HIV RDT for self-testing	CheckNOW HIV SELF TEST	29012-9001	RoW	Abbott Rapid Diagnostics Jena GmbH	Liedtstedter Str. 103-105, Jena, Germany	1 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-checknow-hiv-self-test-page-0481-033-00
2022	HIV RDT	Trinscreen HIV	5551100	RoW	Trinity Biotech Manufacturing Ltd	1 Southern Cross DA Business Park in Bray, Ireland	100 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-trinscreen-hiv-page-0472-052-00
2021	HCV NAT	# cobas HCV (Quantitative nucleic acid test for use on cobas 5800/6800/8800 Systems)	08977321190 09040765190	CE-marked	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit, 192 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-hcv-cobas-PQDs-0465-046-00
2021	Syphilis RDT	First Response Syphilis Anti-TP Card Test	P03FRC25, P03FRC50, P03FRC100, P03FRC25-SA	RoW	Premier Medical Corporation Private Limited	slw 1: A1-302, GIDC, Sarigam 396 195, Valsad, Gujarat, India slw 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Damani, Daman 396216, India	25 T/kit, 50 T/kit, 100 T/kit, 25 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-first-response-syphilis-anti-tp-card-test-page-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/WHOQPP/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-5800/6800/8800-systems-page
2020	HIV RDT	# MERISCREEN HIV 1-2 WB	HVWRPD-01 HVWRPD-02 HVWRPD-06 HVWRPD-07 HVWRPD-08 HVWRPD-09 HVWRPD-10 HVWRPD-11 HVWRPD-12	CE-marked	Merit Diagnostics Pvt. Ltd.	Second Floor, D1-03, Merit Park, Survey No 135/2/B & 174/2, Mukundan Marg, Chola, 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/prequal/WHOQPP/public-report-meriscreen-hiv-1-2-wb-page-0466-074-00
2020	Malaria RDT	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	302030025, 302030005, 302030005, 302030025, 302030010, 302030025(1T)	CE-marked	Orchid Biomedical Systems - A Division of Tulip Diagnostics (P) Ltd	Plot nos 88/89, Phase II, C, Verma Industrial Estate, Varma, Co. 403722, India	11 T/kit, 5 T/kit, 10 T/kit, 25 T/kit, 100 T/kit, 25 x 1 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-paracheck-pf-rapid-test-for-p-falciparum-malaria-device-ver-3-page-0321-004-00
2020	Malaria RDT	One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag	MHWRPD-02, MHWRPD-03, MHWRPD-04, MHWRPD-05	CE-marked	Merit Diagnostics Pvt. Ltd	Second Floor, D1-03, Merit Park, Survey No 135/2/B & 174/2, Mukundan Marg, Chola, Vapi, 396191, India	30 T/kit, 10 T/kit, 25 T/kit, 50 T/kit	https://extranet.who.int/prequal/WHOQPP/public-report-one-step-test-malaria-pf-pan-ag-meriscreen-malaria-pf-pan-ag-page-0336-074-00

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2020	CD4 Technologies	VISITECT CD4 Advanced Disease	A8376	CE -marked	Acculio Ltd	Acculio Ltd located at Hillfoots Business Village, Alva, FK22 5DQ United Kingdom.	25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-subject-cd4-advanced-disease-pqafg.pdf/0384-077-00
2020	HIV RDT	STANDARD Q HIV 1/2 Ab 3-Line Test	09HIV300, 09HIV300M	RoW	SD Biosensor, Inc.	Site 1: 74, Oosangangmyeong 4-ro, Oosang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. Site 2: Plot no. 38, Sector 4, MT Manesar, Gurugram, Haryana 122052, India.	25 T/kit 25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-standard-q-hiv-1-2-ab-3-line-test-pqafg.pdf/0385-117-00
2020	Malaria RDT	parascrreen - Rapid test for Malaria Pw/PM	503000025(1T) 503000010; 503000025; 503000050; 503000030	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/qaaweb/WHOIPR/public-report-parascrreen-rapid-test-malaria-pwafg.pdf/0391-025-00
2020	Malaria RDT	Falciviva - Rapid test for Malaria Pw/PM	503010025(1T) 503010010; 503010025; 503010050; 503010030	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/qaaweb/WHOIPR/public-report-falciviva-rapid-test-malaria-pwafg.pdf/0390-024-00
2020	HIV/Syp RDT	STANDARD Q HIV/Syphilis Combo Test	09HIV200	RoW	SD Biosensor, Inc.	Site 1: 74, Oosangangmyeong 4-ro, Oosang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. Site 2: Plot no. 38, Sector 4, MT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-standard-q-hiv-syphilis-combo-test-pqafg.pdf/0382-117-00
2020	HCV NAT	Alinity m HCV	08N50-090; 08N50-080; 08N50-070	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/qaaweb/WHOIPR/public-report-ality-m-hcv-pqafg.pdf/0461-027-00
2020	Malaria RDT	STANDARD Q Malaria P.0/P+ Ag Test	09MAL200	CE -marked	SD Biosensor, Inc.	Site 1: 74, Oosangangmyeong 4-ro, Oosang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. Site 2: Plot no. 38, Sector 4, MT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-standard-q-malaria-pfpr-ag-test-pqafg.pdf/0348-117-00
2020	Malaria RDT	STANDARD Q Malaria P.F Pan Ag Test	09MAL300	CE -marked	SD Biosensor, Inc.	Site 1: 74, Oosangangmyeong 4-ro, Oosang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. Site 2: Plot no. 38, Sector 4, MT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-standard-q-malaria-pfpan-ag-test-pqafg.pdf/0347-117-00
2020	Malaria RDT	STANDARD Q Malaria P.S Ag Test	09MAL100	CE -marked	SD Biosensor, Inc.	Site 1: 74, Oosangangmyeong 4-ro, Oosang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. Site 2: Plot no. 38, Sector 4, MT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-standard-q-malaria-pfs-ag-test-pqafg.pdf/0346-117-00
2020	HCV RDT	STANDARD Q HCV Ab Test	09HCV100	RoW	SD Biosensor, Inc.	Site 1: 74, Oosangangmyeong 4-ro, Oosang-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea. Site 2: Plot no. 38, Sector 4, MT Manesar, Gurugram, Haryana 122052, India.	25 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-standard-q-hcv-ab-test-pqafg.pdf/0360-117-00
2020	HCV EIA	Manolisa HCV Ag Ab ULTRA V2	72561 and 72562	CE -marked	Bio-Rad	1, bd Raymond Frapart, 92400, Marne La Coquette, France and Route de Casvel, 93114, Steenhouille, France	96 T/kit 480 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-manolisa-hcv-ag-ab-ultra-v2-pqafg.pdf/0379-011-00
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/qaaweb/WHOIPR/public-report-abbott-realtime-hcv-pqafg.pdf/0450-017-00
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/qaaweb/WHOIPR/public-report-sure-check-hiv-self-test-pqafg.pdf/0064-006-01
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/qaaweb/WHOIPR/public-report-abbott-realtime-high-risk-hpv-pqafg.pdf/0453-180-00
2019	HIV RDT	First Response HIV 1-2 O Card test (Version 2.0)	P05FRC05; P05FRC10; P05FRC25; P05FRC30; P05FRC40; P05FRC60; P05FRC100	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/qaaweb/WHOIPR/public-report-first-response-hiv-1-2-o-card-test-pqafg.pdf/0368-030-00
2019	HbA1c RDT	Determine HbA1c 2	702942; 702943; 702943 SET	RoW	Abbott Diagnostics Medical Co. Ltd	357 Matsuhisa, Matsudo-shi, 270-2214, Chiba-ken, Japan	20 T/kit 100 T/kit 100 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-determine-hba1c-2-pqafg.pdf/0451-013-00
2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02, and RC89-01	CE -marked	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigohi, Gosen-shi, Niigata, Japan	100 T/kit	https://extranet.who.int/qaaweb/WHOIPR/public-report-architect-hcv-ag-assay-pqafg.pdf/0374-130-00
2019	HIV RDT for self-testing	# Mylan HIV Self Test	AR57001-03; AR57001-03-01; AR57001-03-02; AR57001-03-03	RoW	Atomo Diagnostics Pty. Ltd	Site 1: Atomo Diagnostics Pty Ltd at level 2, 701-703 Parramatta Road, Leichhardt 2040 NSW, Australia Site 2: Lateral Flow Laboratories (LFL) Unit 1 & 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Mulanberg, 7945, South Africa	1 T/kit; 1 T/kit; 1 T/kit;	https://extranet.who.int/qaaweb/WHOIPR/public-report-mylan-hiv-self-test-pqafg.pdf/0320-080-00

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2019	HIV/Syp RDT	First Response HIV-1/2/RpHsils Combo Card Test	120PRC25; 120PRC30; 120PRC50; 120PRC60; 120PRC100	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/WHOOP/public-report-first-response-hiv12/rphsils-combo-card-test-page-0364-010-00
2019	HIV RDT	WONE STEP Anti-HIV (1&2) Test	ITPW02153-TC40 ITPW02153-TC25 ITPW02153-TC40 ITPW02153-TC40SA ITPW02154-TC40	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. 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/WHOOP/public-report-one-step-anti-hiv-12-test-page-0372-017-00
2019	HCV RDT	Rapid Anti-HCV Test	ITPW01153-TC40; ITPW01153-TC25; ITPW01153-TC40	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit	https://extranet.who.int/prequal/WHOOP/public-report-rapid-anti-hcv-test-page-0371-017-00
2019	Malaria RDT	RAbOn Malaria Pf Rapid Malaria Ag Detection Test	00 DKM-R6-MAL-ADK-004-001, 00 DKM-R6-MAL-ADK-004-025, 00 DKM-R6-MAL-ADK-004-030, and 00 DKM-R6-MAL-ADK-004-050	RoW	Advy Chemical Pvt Ltd.,	Plot No A-334,336,338 & A-337 & 339 Road no. 25 & 26, Wagie Industrial Estate Thane 400 604 India	1 T/kit 10 T/kit 25 T/kit 50 T/kit	https://extranet.who.int/prequal/WHOOP/public-report-rapid-malaria-pf-rapid-malaria-ag-detection-test-page-0345-101-00
2019	Malaria RDT	# NuTek Eliminate Malaria Pf and and NuTek Malaria Pf	05FK140; 05FK141; 05FK142; 05FK143 05FK144	CE-marked	Abbott Diagnostics Korea Inc	site 1: 46, Hagal-ro 15 beongil, Gheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea site 2: 55, Borahagall-ro, Gheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	25T/kit; 25T/kit; 17kit x 25 each; 15kit x 25 each 25T/kit	https://extranet.who.int/prequal/WHOOP/public-report-nutek-eliminate-malaria-pf-page-0349-012-00
2019	HIV NAT	m-PIMA HIV-1/2 VL	27015-950	RoW	Abbott Rapid Diagnostics Jena GmbH	Orfaweg 1, D-07745 Jena, Germany	50 cartridges/kit	https://extranet.who.int/prequal/WHOOP/public-report-m-pima-hiv-12-vl-page-0338-012-00
2018	Malaria RDT	First Response Malaria Antigen P. falciparum (HRP2) Card Test	P13PRC25; P13PRC25; P13PRC30	RoW	Premier Medical Corporation Limited	site 1: A1-302, GIDC, Sarigam 396 155, Valad, Gujarat, India; site 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	25 x single kit; 10 x single kit; 25 x multi kit; 30 x multi kit	https://extranet.who.int/prequal/WHOOP/public-report-first-response-malaria-antigen-p-falciparum-hrp2-card-test-page-0283-010-00
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	P13PRC30; P13PRC25; P13PRC25	RoW	Premier Medical Corporation Limited	site 1: A1-302, GIDC, Sarigam 396 155, Valad, Gujarat, India; site 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	10 x single test; 25 x single test; 30 x multi test; 25 x multi test	https://extranet.who.int/prequal/WHOOP/public-report-first-response-malaria-ag-pf-pv-card-test-page-0329-010-00
2018	Malaria RDT	BoLine Malaria Ag P.f/P.v (P.v)	05FK120; 05FK123	CE-marked	Abbott Diagnostics Korea Inc	65 Borahagall-ro, Gheung-gu, Yongin-si, Geonggi-do, South Korea	25T/kit; 17kit	https://extranet.who.int/prequal/WHOOP/public-report-bo-line-malaria-ag-pf-pv-page-0287-012-00
2018	HIV RDT for self-testing	INSTE HIV Self Test	90-1071	RoW	biolytical Laboratories Inc.	Richmond, British Columbia, Canada	1T/kit	https://extranet.who.int/prequal/WHOOP/public-report-inste-hiv-self-test-page-0300-000-00
2018	HIV RDT	One Step HIV-1/2 Whole Blood/Serum/Plasma Test	W006-C4P2, W006-P0040, W006-P0040L, W006-P0047, W006-P0048, W006-C4P2.F, W006-P0049, W006-P0050, W006-P0051, W006-P0052	RoW	Guangzhou Wonfo Biotech Co., Ltd	8 Lufuhuan Road, Science City, Longgang District, Guangzhou, 510661, Republic of China	25T/kit; 25T/kit; 25T/kit; 25T/kit; 25T/kit; 40T/kit; 40T/kit; 40T/kit; 40T/kit; 40T/kit	https://extranet.who.int/prequal/WHOOP/public-report-one-step-hiv-12-whole-blood-serum-plasma-test-page-0327-004-00
2018	Malaria RDT	One Step Test for Malaria Pf/Pv Ag MERSCREEN Malaria Pf/Pv Ag	MFLRPD-02; MFLRPD-05; MFLRPD-04; MFLRPD-05	CE-marked	Merit Diagnostics Pvt. Ltd.	D1-03, Merit Park, Survey No. 1392/B & 17A/2, Muktanand Marg, Chala, Vasp 396191, Gujarat, India	30T/kit; 25T/kit; 50T/kit; 10 T/kit	https://extranet.who.int/prequal/WHOOP/public-report-one-step-test-malaria-pf-pv-ag-meriscreen-malaria-pf-pv-page-0294-074-00
2018	Malaria RDT	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	P13PRC30; P13PRC25a P13PRC25 P13PRC30	RoW	Premier Medical Corporation Limited	site 1: A1-302, GIDC, Sarigam 396 155, Valad, Gujarat, India; site 2: 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	10 x single kit 25 x single kit 25 x multi kit 30 x multi kit	https://extranet.who.int/prequal/WHOOP/public-report-first-response-malaria-ag-pldh-hrp2-combo-card-test-page-0285-010-00
2018	CD4 Technologies	CyFlow Counter System with CD4 easy count kit and CD4N easy count kit	CY 6-3023; 05-8403; and 05-8405	CE-marked	Symex Partec GmbH	site 1: Arndstr. 11a-b, 02628 Görlitz, Germany; and site 2: Exbio Praha s. a. s., Nad Saffnou 341, 252 50 Vesetice, Czech Republic	100 T/kit	https://extranet.who.int/prequal/WHOOP/public-report-cyflow-counter-system-cd4-easy-count-kit-and-cd4n-easy-count-kit-page-0350-081
2018	HPV Virological Technologies	care HPV Test	634015	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/WHOOP/public-report-care-hpv-test-page-0366-028-00
2018	HCV EIA	INNOTEST HCV Ab IV	80068; 80230	CE-marked	Fujirebio Europe NV	Ghent, Belgium	192T/kit 480T/kit	https://extranet.who.int/prequal/WHOOP/public-report-innotest-hcv-ab-iv-page-0301-079-00
2017	HbA1c RDT	BoLine HbA1c WB	01FK120W	RoW	Abbott Diagnostics Korea Inc	Gheung-gu, Republic of Korea	30T/kit	https://extranet.who.int/prequal/WHOOP/public-report-bo-line-hba1c-wb-page-0319-012-00
2017	HIV RDT	Genie Fast HIV 1/2	72327; 72347; 72330	CE-marked	Bio-Rad	Marne La Coquette, France	25T/kit 50T/kit 50T/kit	https://extranet.who.int/prequal/WHOOP/public-report-genie-fast-hiv-1-2-page-0153-031-00
2017	HPV Virological Technologies	Xpert HPV	GXPVP-CE-10	CE-marked	Cepheid AB	Solna, Sweden	10T/kit	https://extranet.who.int/prequal/WHOOP/public-report-xpert-hpv-page-0268-070-00
2017	HIV NAT	Aptima HIV-1 Quant Dx Assay	PRD-G3000 (PRD-G3002, PRD-G3003), 303044, PRD-G3001, and 303095	CE-marked	Hologic, Inc.	San Diego, USA	100T/kit	https://extranet.who.int/prequal/WHOOP/public-report-aptima-hiv-1-quant-dx-assay-page-0246-078-00

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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
2017	HIV RDT for self-testing	OraQuick HIV Self-Test	SMA-3300; SMA-3301; SMA-3302; Country specific variations are documented through a suffix "888" to the product code on the outer packaging (i.e. SMA-3301.001, 002, ...).	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Apurthaya, Thailand	50T/kit; 250T/kit; 110T/kit	https://extranet.who.int/prequal/WHOOP/public-report/oraquick-hiv-self-test.pdf-0139-035-01
2017	HIV NAT	Xpert HIV-1 Viral Load	GMHV VL-CE-10	CE-marked	Cepheid AB	Solna, Sweden	10T/kit	https://extranet.who.int/prequal/WHOOP/public-report/xpert-hiv-1-viral-load-geneamp-dx-geneamp-cd101v-48-geneamp
2017	HCV NAT	Xpert HCV Viral Load	GMHCV VL-CE-10	CE-marked	Cepheid AB	Solna, Sweden	10T/kit	https://extranet.who.int/prequal/WHOOP/public-report/xpert-hcv-viral-load.pdf-0365-070-00
2017	HIV Confirmatory Assay	Genieus HIV 1/2 Confirmatory Assay with Genieus HIV/2 Confirmatory Controls	72460; and 72329	CE-marked	Bio-Rad	Marnes-La-Coquette, France	20T/kit	https://extranet.who.int/prequal/WHOOP/public-report/genieus-hiv-1-2-confirmatory-assay-genieus-hiv-1-2-confirmatory-controls.pdf-0383
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1203-0270; 001-0274	CE-marked	OraSure Technologies, Inc.	Bethlehem, USA	25T/kit; 100T/kit	https://extranet.who.int/prequal/WHOOP/public-report/oraquick-hiv-12-rapid-antibody-test.pdf-0139-035-00
2016	HIV RDT	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	B-401-SO-C-2; KH-R-02; and A-GOLD-01	RoW	Shanghai Kehua Bio-engineering Co., Ltd.	Shanghai, PR China	50T/kit	https://extranet.who.int/prequal/WHOOP/public-report/diagnostic-kit-hiv-1-2-antibody-colloidal-gold-v2.pdf-0367-037-00
2016	HCV RDT	Baseline HCV	02PK30; 02PK36; 02PK17	RoW	Abbott Diagnostics Korea Inc	Gilheung-gu, Republic of Korea	30T/kit; 25T/kit; 30T/kit	https://extranet.who.int/prequal/WHOOP/public-report/baseline-hcv.pdf-0357-012-00
2016	HIV RDT	Determine HIV Early Detect	702842; 702843; 702846/SET	RoW	Alere Medical Co. Ltd.	Matsudo-shi, Chiba-ken, Japan	20T/kit; 100T/kit; 100T/kit	https://extranet.who.int/prequal/WHOOP/public-report/determine-hiv-early-detect.pdf-0343-014-00
2016	HIV NAT	Xpert HIV-1 Qual Assay	GMHV-QA-CE-10	CE-marked	Cepheid AB	Solna, Sweden	10 cartridges/kit and instrument	https://extranet.who.int/prequal/WHOOP/public-report/xpert-hiv-1-qual-assay.pdf-0269-070-00
2016	HIV NAT	# m-PIMA HIV 1/2 Detect	27011R050 27030R001	CE-marked	Alere Technologies GmbH	Jena, Germany	50 cartridges/kit instrument	https://extranet.who.int/prequal/WHOOP/public-report/m-pima-hiv-1-2-detect.pdf-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/WHOOP/public-report/dpp-hiv-1-2-assay.pdf-0053-006-00
2016	HIV RDT	OraQuick HIV 1/2 Rapid Antibody Test	Sw-0020; Sw-0014; SMA-0062; Sw-0023; Sw-0033	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Apurthaya, Thailand	100T/kit; 100T/kit; 100T/kit; 500T/kit; 500T/kit	https://extranet.who.int/prequal/WHOOP/public-report/oraquick-hiv-12-rapid-antibody-test.pdf-0139-035-00
2016	HBsAg EIA	DS-EIA HBsAg 0.01	B-1254/L1.2; B-1252/L1.2; B-1253/L1.2; B-1256/L1.2; B-251/L1.2	CE-marked	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/kit; 192T/kit; 480T/kit; 96T/kit (for detection) or 48T/kit (for confirmation) 240T/kit	https://extranet.who.int/prequal/WHOOP/public-report/gs-size-192ds-003-immune-immunosay-detection-and-confirmation-hepatitis-b
2016	HIV Confirmatory Assay	MP Diagnostics HIV Blot 2.2	11030-026; 11030-036	CE-marked	MP Biomedicals Asia Pacific Pte Ltd.	Singapore, Singapore	18T/kit; 36T/kit	https://extranet.who.int/prequal/WHOOP/public-report/mp-diagnostics-hiv-blot-2-2.pdf-0338-071-00
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/WHOOP/public-report/a-anti-hiv-1-2-elisa.pdf-0006-005-00
2016	HIV RDT	Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	WI-5810; WI-5810C; WI-5850; WI-5850C; WI-5810EL; WI-5850EL; WI-5810EL; WI-5850EL; WI-5810; WI-5850; WI-5810EL; WI-5850EL	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	10T/kit; 10T/kit; 50T/kit; 50T/kit; 10T/kit; 50T/kit; 50T/kit; 10T/kit; 10T/kit; 50T/kit; 50T/kit; 10T/kit; 50T/kit	https://extranet.who.int/prequal/WHOOP/public-report/rapid-test-antibody-human-immunodeficiency-virus-hiv-colloidal-gold-device.pdf
2015	CD4 Technologies	Aquios C1 flow cytometer	830166; 839101; 839102; 825697; 825698; 823534; 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/WHOOP/public-report/aquios-c1-flow-cytometer.pdf-0166-063-00
2015	HIV/Syp RDT	Baseline HIV/Syphilis Duo	06PK30; 06PK35; 06PK37	RoW	Abbott Diagnostics Korea Inc	Gilheung-gu, Republic of Korea	25T/kit; 25T/kit; 25T/kit	https://extranet.who.int/prequal/WHOOP/public-report/baseline-hiv/syphilis-duo.pdf-0179-012-00

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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	Biotline Malaria Ag P.FIP.v	05FKB2; 05FKB3; 05FKB2; 05FKB3; 05FKB6; 05FKB7	CE -marked	Abbott Diagnostics Korea Inc	Gihyeung-gu, Republic of Korea	25T/kit; 25T/kit; 17/kit x25 each 17/kit x25 each 10T/kit; 25T/kit	https://extranet.who.int/prequal/WHOCP/public-report-biotline-malaria-ag-pfip-pvds-0125-012-00
2015	Malaria RDT	Biotline Malaria Ag P.F. (HRP2) (pLDH)	05FKB0; 05FKF03; 05FKB3; 05FKB6; 05FKB2	CE -marked	Abbott Diagnostics Korea Inc	Gihyeung-gu, Republic of Korea	25T/kit; 17/kit x25 each 25T/kit; 17/kit x 25 each	https://extranet.who.int/prequal/WHOCP/public-report-biotline-malaria-ag-pf-hrp2-pdh-pvds-0209-012-00
2015	HCV EIA	INNO-LIA HCV Score	80538	CE -marked	Fujirebio Europe NV	Zwijnaarde, Belgium	20T/kit	https://extranet.who.int/prequal/WHOCP/public-report-inno-lia-hcv-score-pvds-0202-073-00
2015	HIV EIA	DS-EIA-HIV-AGAB-SCREEN	1-1604/L, 2; 1-1602/L, 2; 1-1606/L, 2	CE -marked	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/A plastic; 135T/9 plates; 480 T/5 plates	https://extranet.who.int/prequal/WHOCP/public-report-ds-eia-hiv-agab-screen-pvds-0106-038-00
2015	Malaria RDT	**CareStart Malaria HRP2 (pLDH) (PF/PAN) COMBO	multi kit (product codes: RMRM-02571; RMRM-02571CB; RMRM-02571RB; RMRM-02571R; RMRM-05071; RMRM-05071CB; RMRM-05071RB and RMRM-05071R) single kit (product codes: RMRU-02571; RMRU-02571CB; RMRU-02571RB; RMRU-02571R; RMRU-05071; RMRU-05071CB; RMRU-05071RB and RMRU-05071R)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit; 25T/kit; 40T/kit.	https://extranet.who.int/prequal/WHOCP/public-report-carestart-malaria-hrp2-pdh-pfpan-combo-pvds-0138-048-00
2015	Malaria RDT	**CareStart Malaria HRP2 (PF)	multi kit (product codes: RMCOM-02571; RMCOM-02571CB; RMCOM-02571RB; RMCOM-02571R; RMCOM-05071; RMCOM-05071CB; RMCOM-05071RB and RMCOM-05071R) single kit (product codes: RMCOU-02571; RMCOU-02571CB; RMCOU-02571RB; RMCOU-02571R; RMCOU-05071; RMCOU-05071CB; RMCOU-05071RB and RMCOU-05071R)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit; 25T/kit; 40T/kit;	https://extranet.who.int/prequal/WHOCP/public-report-carestart-malaria-hrp2-pf-pvds-0137-049-00
2015	Malaria RDT	**CareStart Malaria HRP2 (pLDH) (PF/PN) COMBO	multi kit (product codes: RMMV-02571; RMMV-02571CB; RMMV-02571RB; RMMV-02571R; RMMV-05071; RMMV-05071CB; RMMV-05071RB and RMMV-05071R) single kit (product codes: RMMVU-02571; RMMVU-02571CB; RMMVU-02571RB; RMMVU-02571R; RMMVU-05071; RMMVU-05071CB; RMMVU-05071RB and RMMVU-05071R)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit; 25T/kit; 40T/kit	https://extranet.who.int/prequal/WHOCP/public-report-carestart-malaria-hrp2-pdh-pfpan-combo-pvds-0138-048-00
2015	Malaria RDT	**CareStart Malaria HRP2 (pLDH) (PF)	multi kit (product codes: RMPM-02571; RMPM-02571CB; RMPM-02571RB; RMPM-02571R; RMPM-05071; RMPM-05071CB; RMPM-05071RB and RMPM-05071R) single kit (product codes: RMPFU-02571; RMPFU-02571CB; RMPFU-02571RB; RMPFU-02571R; RMPFU-05071; RMPFU-05071CB; RMPFU-05071RB and RMPFU-05071R)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit; 25T/kit; 40T/kit	https://extranet.who.int/prequal/WHOCP/public-report-carestart-malaria-hrp2-pdh-pf-pvds-0138-049-00
2015	Malaria RDT	**CareStart Malaria (pLDH) (PAN)	multi kit (product codes: RMMN-02571; RMMN-02571CB; RMMN-02571RB; RMMN-02571R; RMMN-05071; RMMN-05071CB; RMMN-05071RB and RMMN-05071R) single kit (product codes: RMMNU-02571; RMMNU-02571CB; RMMNU-02571RB; RMMNU-02571R; RMMNU-05071; RMMNU-05071CB; RMMNU-05071RB and RMMNU-05071R)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit; 25T/kit; 40T/kit	https://extranet.who.int/prequal/WHOCP/public-report-carestart-malaria-pdh-pn-pvds-0134-049-00
2015	HIV Confirmatory Assay	INNO-Lia HIV i18 Score	80540	CE -marked	Fujirebio Europe NV	Ghent, Belgium	20T/kit	https://extranet.who.int/prequal/WHOCP/public-report-inno-lia-hiv-i18-score-pvds-0203-073-00
2015	HIV EIA	Murex HIV Ag/Ab Combination	7G79-09 (G541, 96 wells); and 7G79-11 (G542, 480 wells)	CE -marked	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit	https://extranet.who.int/prequal/WHOCP/public-report-murex-hiv-agab-combination-pvds-0144-043-00
2014	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	06690881190; 03051315001; 03279813001; 03587797190; 06988611190; 05807875001; 0315440001; and 281327887001	CE -marked	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	48T/kit	https://extranet.who.int/prequal/WHOCP/public-report-cobas-ampliprep-cobas-taqman-hiv-1-qualitative-test-v20-taqman-48-pvds-0221
2014	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	06690881190; 03587797190; 06988611190; 03051315001; 03121435001; 281327887001; 05807875001; and 0315440001	CE -marked	Roche Diagnostics GmbH	Mannheim, Germany	48T/kit	https://extranet.who.int/prequal/WHOCP/public-report-cobas-ampliprep-cobas-taqman-hiv-1-qualitative-test-v20-taqman-96-pvds-0200
2014	HIV RDT	SURE CHECK HIV 1/2 Assay	HIV201 (BD-9527-05)	RoW	Chembio Diagnostic Systems Inc.	Madison, NY, USA	25T/kit	https://extranet.who.int/prequal/WHOCP/public-report-sure-check-hiv-12-assay-pvds-0054-006-00
2014	HBsAg EIA	Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3	9F80-01; 9F80-05; 2527-01	CE -marked	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit; 50T/kit	https://extranet.who.int/prequal/WHOCP/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pvds-0121-043-00

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2014	Malaria RDT	ParasIT Fiver. 1.0 Rapid Test for P.falciparum Malaria Device	SSIC104-50; SSIC104-25; SSIC104-50	CE-marked	ARKRAY Healthcare Pvt. Ltd.	Sachin (Surat), India	10T/kit; 25T/kit; 50T/kit	https://extranet.who.int/prequal/WMO/PQ/public-report-parasit-f-ver-10-rapid-test-p-falciparum-malaria-device-page-0062-023-06
2014	CD4 Technologies	BD FACSPresto Near-Patient CD4 Counter with BD CD4NCDA/Ino 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/bottle) 655495: pipette (100/bottle)	https://extranet.who.int/prequal/WMO/PQ/public-report-bd-facspresto-near-patient-cd4-counter-system-page-0321-045-00
2014	HIV RDT	ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	HH1402N6F, HH1402N6A, HH1402N6G, HH1402N6B, HH1402N6D, HH1402N6E, HH1402N6F	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/WMO/PQ/public-report-abon-hiv-1-2-o-tri-line-human-immunodeficiency-virus-rapid-test-device-page-0143
2013	HIV RDT	INSTI HIV-1/HIV-2 Antibody Test	90-1033; 90-1022; 90-1021; 90-1026; 90-1064	RoW	Biolytical Laboratories, Inc.	Richmond, British Columbia, Canada	24T/kit without support material; 24T/kit with support materials; 48T/kit without support material; 48T/kit with support materials; 48T/kit with glycerol but no sucrose, no alcohol swabs; 48T/kit with no support materials;	https://extranet.who.int/prequal/WMO/PQ/public-report-insti-hiv-1-2-antibody-test-page-0062-002-00
2013	Malaria RDT	Bioline Malaria Ag P fPan	05FK60; 05FK61; 05FK62; 05FK63; 05FK67	CE-marked	Abbott Diagnostics Korea Inc	Gihungu, Republic of Korea	25T/kit; 25x17/kit; 1T/kit; 25T/kit; 30T/kit	https://extranet.who.int/prequal/WMO/PQ/public-report-bioline-malaria-ag-pfpan-page-0030-012-01
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	96T/kit; 4x24T pack	https://extranet.who.int/prequal/WMO/PQ/public-report-abbott-realtime-hiv-1-qualitative-manual-page-0153-027-00
2013	HIV NAT	Abbott RealTime HIV-1 Qualitative (in 2000µl)	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	96T/kit; 4x24T pack	https://extranet.who.int/prequal/WMO/PQ/public-report-abbott-realtime-hiv-1-qualitative-in-2000ul-page-0048-021-00
2013	HIV RDT	Bioline HIV-1/2 3.0	03FK30; 03FK36; 03FK17	RoW	Abbott Diagnostics Korea Inc	Gihungu, Republic of Korea	30T/kit; 25T/kit; 25T/kit	https://extranet.who.int/prequal/WMO/PQ/public-report-bioline-hiv-1-2-30-page-0017-012-00
2013	HIV EIA	Genscreen ULTRA HIV Ag-Ab	72386; and 72388	CE-marked	Bio-Rad	Marnes La Coquette, France	96T/kit; 480T/kit	https://extranet.who.int/prequal/WMO/PQ/public-report-genscreen-ultra-hiv-ag-ab-page-0096-031-00
2012	HIV RDT	Uni-Gold HIV	206502; 1206502N; 1206502E; 1206502N 100; 1206502 100; 1206502-C; 1206502E-C; 1206502-C100	RoW	Trinity Biotech Manufacturing Ltd.	Bray, Ireland	20T/kit; 20T/kit; 20T/kit; 100T/kit; 100T/kit; 20T/kit; 20T/kit; 100T/kit	https://extranet.who.int/prequal/WMO/PQ/public-report-uni-gold-hiv-page-0149-052-00
2012	CD4 Technologies	Pima CD4 Test	260100025 and 260300003; 260100100; and 260300003	CE-marked	Abbott Rapid Diagnostics Jena GmbH	Ortaweg 1, D-07743 Jena, Germany	25 cartridges/kit and instrument; 100 cartridges/kit and instrument	https://extranet.who.int/prequal/WMO/PQ/public-report-pima-cd4-test-page-0099-032-00
2012	CD4 Technologies	BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (Absolute CD4, CD39, 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/WMO/PQ/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/WMO/PQ/public-report-bd-facscount-instrument-system-facscount-control-kit-and-bd-facscount-cd4
2012	HIV NAT	COBAS AmpliPhy/COBAS TagMan HIV-1 Test, version 2.0 (TagMan 48)	05212294190; 03587797190; 03121453001; 03051315001 or 03807875001 and 07963084190; Optional: 05127503001; 28127387001	CE-marked	Roche Diagnostics GmbH	Mannheim, Germany	05212294190: 48T/kit 03587797190: 5.1.1 liters	https://extranet.who.int/prequal/WMO/PQ/public-report-cobas-ampli-phy-cobas-tagman-hiv-1-test-version-20-tagman-48-page-0129-046-00
2012	HIV NAT	COBAS AmpliPhy/COBAS TagMan HIV-1 Test, version 2.0 (TagMan 96)	05212294190; 03587797190; 03279832001; 03051315001; 07479080001 or 03807875001 and 07963084190; Optional: 05127503001; 28127387001	CE-marked	Roche Molecular Systems, Inc.	Branchburg, NJ, USA	05212294190: 48T/kit 03587797190: 5.1.1 liters	https://extranet.who.int/prequal/WMO/PQ/public-report-cobas-ampli-phy-cobas-tagman-hiv-1-test-version-20-tagman-96-page-0147-046-00

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Last update: 19 April 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
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 TP5, Taman Perindustrian, USF, 47000, Subang Jaya, Selangor, Malaysia	207/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-hiv-1-2-stat-pak-pqdr-0007-006-06
2011	HIV NAT	NuclSENS EasyQ HIV-1 v2.0 (Automated)	280140; 280130; 280131; 280132; 280133; 280134; 285056; 200309; and 285053	CE-marked	bioMérieux SA	Marcy L'Etoile, France	280130; 280131; 280132; 280133 and 280134: 4x1L 285056: 48 L/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-nuclsens-easyq-hiv-1-v2-0-automated-pqdr-0127-0106-00
2011	HIV NAT	NuclSENS 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 L/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-nuclsens-easyq-hiv-1-v2-0-semi-automated-pqdr-0148-016-00-0
2011	HIV RDT	Determine HIV 1/2	702340; 702340; 702343SET and 702343SETL	RoW	Abbott Diagnostics Medical Co., Ltd	Matsumoto-shi, Chiba-ken, Japan	207/kit; 100T/kit; 100T/kit; 100T/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-determine-hiv-1-2-pqdr-0013-013-00
2011	HIV NAT	Abbott RealTime HIV-1 (Manual)	2G31 (2G31-90; 2G31-80; 2G31-70); 2G31-66; 1168-09; 9K13-01; 0470-24; and 0471-93	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); 0470-24: 96T/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-abbott-realtime-hiv-1-manual-pqdr-0146-037-00
2011	HIV NAT	Abbott RealTime HIV-1 (m 2000sp)	2G31 (2G31-90 or 2G31-010; 2G31-80; 2G31-70); 2G31-66; 1168-09; 9K13-01; 0470-24; 0471-93; and 9K14-02	CE-marked	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T) or 2G31-010: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 0470-24: 96T/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-abbott-realtime-hiv-1-m2000sp-pqdr-0145-092-00
2011	HIV NAT	Abbott RealTime HIV-1 (m 34sp)	3N06-01; 2G31 (2G31-90; 2G31-80; 2G31-70); 2G31-66; 1168-09; 9K13-01; 0470-24; and 0471-93	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); 0470-24: 96T/kit	https://extranet.who.int/prsqul/WHOCPW/public-report-abbott-realtime-hiv-1-m34sp-pqdr-0083-027-00
2010	Malaria RDT	Biotline Malaria Ag P f	05FK02; 05FK01; 05FK02; 05FK03	CE-marked	Abbott Diagnostics Korea Inc	Gilheung-ku, Republic of Korea	25T/kit; 25T/kit; 1T/kit x 25 each; 1T/kit x 25 each.	https://extranet.who.int/prsqul/WHOCPW/public-report-biotline-malaria-ag-pf-pqdr-0013-012-01

** 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
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	HIV102	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	VITEK HIV 1/2	31112	BioMérieux SA	Withdrawal by the manufacturer.
2021	HbA1c Assay	VITEK HbA1c	31124	BioMérieux SA	Withdrawal by the manufacturer.
2020	HCV Assay	Siovelia HCV 4.0	3000-1115 and 3000	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV Serology	Siovelia HIV 1+2 Ag/Ab	3000-1172 and 3000-1173	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HbA1c Assay	Siovelia HbA1c 3.0	3000-1158 and 3000-1159	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV RDT	One Response HIV 1-2-0 Card Test	05FRC100; 05FRC60; 05FRC30; and 05FRC02	Premier Medical Corporation Private Limited	Discontinuation of the product by the manufacturer.
2019	HCV Assay	Murex anti-HCV (version 4.0)	7951-05 and 7951-02	Diaplin South Africa (Pty) Ltd	Withdrawal by the manufacturer.
2019	HIV DA	Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost/TMB	OPR03S; OPR03S; OPR03S(Q); and OLV175	Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH
2019	HbA1c Assay	Enzygnost HbA1c 6.0 and Supplementary reagents kit for Enzygnost/TMB	OPH03S and OPH05S	Siemens Healthcare Diagnostics Products GmbH	Siemens Healthcare Diagnostics Products GmbH
2018	HIV RDT	SD Biotline 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	ParasIT T Var. 1.0 Rapid Test for P. falciparum Malaria Dipstick	58AC109-50; 58AC109-25 and 58AC109-50	Ankay Healthcare Private Limited	Failure to meet product testing acceptance criteria.

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