

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2023	HIV NAT	SAMBA II HIV-1 Qual Whole Blood Test	4500-12	CE-mark	Diagnostics for the Real World Ltd	Diagnostics for the Real World in San Jose, CA, USA	12 T/kit
2023	HPV Virological Technologies	cobas HPV	07460155190, 07460171190, 07002238190, 06997546190, 06997511190, 06997538190, 06997503190	CE-mark	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	480 T/kit
2022	Syphilis RDT	Determine Syphilis TP	7D2452, 7D2453 and 7D2453SET	RoW	Abbott Diagnostics Medical Co., Ltd.	Abbott Diagnostics Medical Co., Ltd, located at 357 Matsuhidai, Chiba-ken Matsudo-shi, 270-2214, Japan	30 T/kit 100 T/kit 100 T/kit
2022	HCV NAT	Xpert HCV VL Fingerstick	GXHCV-F5-CE-10	CE-mark	Cepheid AB	Röntgenvägen 5, SE-171 54 Solna, Sweden	10 T/kit
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
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
2022	HIV NAT	cobas HIV-1 Nucleic acid test for use on the cobas 4800 System	08792992190, 06979572190, 06979513190, 06979521190, 05235863190, 05235871190, 06979556190, 06979530190,	CE-mark	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit; 10 Sets; 240 T/kit; 960 T/kit; 240 T/kit; 960 T/kit; 240 T/kit; 240 T/kit;
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 100T/kit
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
2022	HIV RDT	TrinScreen HIV	5551100	RoW	Trinity Biotech Manufacturing Ltd	1 Southern Cross IDA Business Park in Bray, Ireland	100 T/kit
2021	HIV NAT	# cobas HIV-1 Quantitative nucleic acid test for use on the cobas 4800 System	06979599190; 06979572190; 06979513190; 06979521190; 05235863190; 05235871190; 06979556190; 06979530190 ; 06979548190	CE-mark	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit; 10 Sets; 240 T/kit; 960 T/kit; 240 T/kit; 960 T/kit; 240 T/kit; 240 T/kit; 960 T/kit
2021	HCV NAT	# cobas HCV (Quantitative nucleic acid test for use on cobas 5800/6800/8800 Systems)	6997732190 09040765190	CE-mark	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/Kit
2021	Syphilis RDT	First Response Syphilis Anti-TP Card Test	PI08FRC25, PI08FRC50 PI08FRC100 PI08FRC25-SA	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

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2020	HIV NAT	# cobas HIV-1 Quantitative nucleic acid test for use on the cobas 5800/6800/8800 Systems	07000995190 09040803190	CE-mark	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/Kit
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-mark	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 25 T/kit 30 T/kit 40 T/kit 60 T/kit
2020	Malaria RDT	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	302030025, 302030005, 302030010, 302030025, 302030100, 302030025(1T)	CE-mark	Orchid 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, 5 T/kit 10 T/kit 25 T/kit 100 T/kit 25 x 1 T/kit
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-mark	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
2020	CD4 Technologies	# VISITECT CD4 Advanced Disease	AB376	CE-mark	AccuBio Ltd	AccuBio Ltd located at Hillfoots Business, Village, Alva, FK12 5DQ United Kingdom.	25 T/kit
2020	HIV RDT	STANDARD Q HIV 1/2 Ab 3-Line Test	09HIV30D; 09HIV30DM	RoW	SD Biosensor, Inc	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit; 25 T/kit
2020	Malaria RDT	parascreen - Rapid test for Malaria Pan/Pf	503030025(1T) 503030010; 503030025; 503030050; 503030100	CE-mark	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
2020	Malaria RDT	# Falcivax - Rapid test for Malaria Pv/Pf	503010025(1T) 503010010; 503010025; 503010050; 503010100	CE-mark	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
2020	HIV/Syp RDT	STANDARD Q HIV/Syphilis Combo Test	09HIV20D	RoW	SD Biosensor, Inc	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit
2020	HCV NAT	# Alinity m HCV	08N50-090; 08N50-080; 08N50-070	CE-mark	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
2020	Malaria RDT	STANDARD Q Malaria P.f/P.v Ag Test	09MAL20D	CE-mark	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit
2020	Malaria RDT	STANDARD Q Malaria P.f Pan Ag Test	09MAL30D	CE-mark	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2020	Malaria RDT	STANDARD Q Malaria P.f Ag Test	09MAL10D	CE-mark	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit
2020	HCV RDT	STANDARD Q HCV Ab Test	09HCV10D	RoW	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit
2020	HCV EIA	Monolisa HCV Ag-Ab ULTRA V2	72561 and 72562	CE-mark	Bio-Rad	3, bd Raymond Poincaré, 92430, Marne La Coquette, France and Route de Cassel, 59114, Steenvoorde, France	96 T/kit 480 T/kit
2019	HCV NAT	Abbott RealTime HCV	4J86-90; 4J86-80; and 4J86-70	CE-mark	Abbott Molecular Inc	1300 East Touhy Avenue, Des Plaines, IL 60018 USA	96 T/kit
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
2019	HPV Virological Technologies	Abbott RealTime High Risk HPV	02N09-092; and 02N09-080	CE-mark	Abbott GmbH	Max-Planck-Ring 2, Wiesbaden, 65205, Germany	96 T/kit
2019	HIV RDT	First Response HIV 1-2.O Card test (Version 2.0)	PI05FRC05; PI05FRC10; PI05FRC25; PI05FRC30; PI05FRC50; PI05FRC60; PI05FRC100	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
2019	HBsAg RDT	# Determine HBsAg 2	7D2942; 7D2943; 7D2943 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
2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02; and 8C89-01	CE-mark	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, Japan	100 T/kit
2019	HIV RDT for self-testing	# Mylan HIV Self Test	ARST001-03; ARST001-03-01; ARST001-03-02; ARST001-03-03	RoW	Atomo Diagnostics Pvt. 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, Muizenberg, 7945, South Africa	1 T/kit; 1 T/kit; 1 T/kit; 1 T/kit.
2019	HIV/Syp RDT	# First Response HIV1+2/Syphilis Combo Card Test	I20FRC25; I20FRC30; I20FRC50; I20FRC60; I20FRC100	RoW	Premier Medical Corporation Private Limited	Sarigam, Gujarat, India	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit
2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40; ITPW02152-TC25; ITPW02153-TC40 ITPW02153-TC40SA	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

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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, 361022, China	40 T/kit 25 T/kit 40 T/kit
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
2019	Malaria RDT	# NxTek Eliminate Malaria Pf and and NxTek Malaria Pf	05FK140; 05FK141; 05FK142; 05FK143 05FK144	CE-mark	Abbott Diagnostics Korea Inc	site 1: 46, Hagal-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 25T/Kit
2019	HIV NAT	# m-PIMA HIV-1/2 VL	27015-W50	RoW	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1, D-07743 Jena, Germany	50 cartridges/kit
2018	Malaria RDT	First Response Malaria Antigen P. falciparum (HRP2) Card Test	PI13FRC25s; PI13FRC10s; PI13FRC25; PI13FRC30	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 x single kit; 10 x single kit; 25 x multi kit; 30 x multi kit
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	PI19FRC10s; PI19FRC25s; PI19FRC30; PI19FRC25	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 x single test; 30 x multi test; 25 x multi test
2018	Malaria RDT	Bioline Malaria Ag P.f/P.v	05FK120; 05FK123	CE-mark	Abbott Diagnostics Korea Inc	65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea	25T/kit; 1T/kit
2018	HIV RDT for self-testing	INSTI HIV Self Test	90-1071	RoW	bioLytical Laboratories Inc.	Richmond, British Columbia, Canada	1T/kit
2018	HIV RDT	One Step HIV1/2 Whole Blood/Serum/Plasma Test	W006-C4P2, W006-P0045, W006-P0046, W006-P0047, W006-P0048, W006-C4P2-F, W006-P0049, W006-P0050, W006-P0051,	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	25T/kit; 25T/kit; 25T/kit; 25T/kit; 25T/kit; 40T/kit; 40T/kit; 40T/kit; 40T/kit;
2018	Malaria RDT	One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02; MFLRPD-03; MFLRPD-04; MFLRPD-05	CE-marked	Meril Diagnostics Pvt. Ltd.	D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India	30T/kit; 25T/kit; 50T/kit; 10 T/kit.
2018	Malaria RDT	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC10s PI16FRC25s PI16FRC25 PI16FRC30	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 x single kit 25 x single kit 25 x multi kit 30 x multi kit

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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	Symex Partec GmbH	site 1: Arndtstr. 11a-b, 02826 Görlitz, Germany; and site 2: Exbio Praha a.s., Nad Safinou II 341, 252 50 Vestec, Czech Republic	100 T/kit
2018	HPV Virological Technologies	care HPV Test	614015	CE-mark	QIAGEN GmbH	site 1: QIAGEN Sciences, Germantown, 20874, United States site 2: QIAGEN Shenzhen Co., Shenzhen China	96 T/kit
2018	HCV EIA	INNOTEST HCV Ab IV	80068; 80330	CE-mark	Fujirebio Europe NV	Ghent, Belgium	192T/kit 480T/kit
2017	HBsAg RDT	Bioline HBsAg WB	01FK10W	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit
2017	HIV RDT	Genie Fast HIV 1/2	72327; 72347; 72330	CE-mark	Bio-Rad	Marne La Coquette, France	25T/kit 50T/kit 50T/kit
2017	HPV Virological Technologies	Xpert HPV	GXHPV-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit
2017	HIV NAT	Aptima HIV-1 Quant Dx Assay	PRD-03000 (PRD-03002, PRD-03001); 303014; PRD-03003; and 303095	CE-mark	Hologic, Inc.	San Diego, USA	100T/kit
2017	HIV RDT for self-testing	OraQuick HIV Self-Test	5X4-1000; 5X4-1001; 5X4-2001; Country specific variations are documented through a suffix "###" to the product code on	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand	50T/kit; 250T/kit; 110T/kit
2017	HIV NAT	# Xpert HIV-1 Viral Load	GXHIV-VL-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit
2017	HCV NAT	Xpert HCV Viral Load	GXHCV-VL-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit
2017	HIV Confirmatory Assay	Geenius HIV 1/2 Confirmatory Assay with Geenius HIV1/2 Confirmatory Controls	72460; and 72329	CE-mark	Bio-Rad	Marnes-La-Coquette, France	20T/kit
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1001-0270; 001-0274	CE-mark	OraSure Technologies, Inc.	Bethlehem, USA	25T/kit; 100T/kit
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	50T/kit
2016	HCV RDT	Bioline HCV	02FK10; 02FK16; 02FK17	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit 25T/kit 30T/kit
2016	HIV RDT	# Determine HIV Early Detect	7D2842; 7D2843; 7D2843SET	RoW	Alere Medical Co. Ltd.	Matsudo-shi, Chiba-ken, Japan	20T/kit; 100T/kit; 100T/kit
2016	HIV NAT	Xpert HIV-1 Qual Assay	GXHIV-QA-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10 cartridges/kit and instrument

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2016	HIV NAT	m-PIMA HIV-1/2 Detect	270110050; 270110010; 27011-W50 270300001	CE-mark RoW	Alere Technologies GmbH	Jena, Germany	50 cartridges/kit 10 cartridges/kit 50 cartridges/kit Instrument
2016	HIV RDT	DPP HIV 1/2 Assay	65-9506-0	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	20T/kit
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
2016	HBsAg EIA	DS-EIA-HBsAg-0,01	B-1254/1.2; B-1252/1.2; B-1255/1.2; B-1256/1.2; B-231/1.2	CE-mark	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/kit; 192T/kit; 480T/kit; 96T/kit (for detection) or 48T/kit(for confirmation) 200T/kit
2016	HIV Confirmatory Assay	MP Diagnostics HIV Blot 2.2	11030-018; 11030-036	CE-mark	MP Biomedicals Asia Pacific Pte.Ltd.	Singapore, Singapore	18T/kit; 36T/kit
2016	HIV EIA	AiD anti-HIV 1+2 EUSA	WI-4396; WI-43480	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	96T/kit; 480T/kit
2016	HIV RDT	Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	WJ-1810; WJ-1810E; WJ-1850; WJ-1850E; WJ-1810EL; WJ-1850EL; WJ-18510EL;	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	10T/kit 10T/kit; 50T/kit; 50T/kit; 10 T/kit; 50 T/kit; 10 T/kit;
2015	CD4 Technologies	Aquios CL flow cytometer	B30166; B39101; B39102; B25697; B25698; B23536; B23538; B23533; B23534; B23535; B25700; and B23502	CE-mark	Beckman Coulter Life Sciences	site 1: Miami, FL, USA (instrument site) site 2: Hialeah, FL, USA (reagent site)	50T/kit
2015	HIV/Syp RDT	Bioline HIV/Syphilis Duo	06FK30; 06FK35; 06FK37	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 25T/kit; 25T/kit.
2015	Malaria RDT	Bioline Malaria Ag P.f/P.v	05FK80; 05FK81; 05FK82; 05FK83; 05FK86; 05FK87	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 25T/kit 1T/kit x25 each 1T/kit x25 each 10T/kit 25T/kit
2015	Malaria RDT	Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90; 05FKFK93; 05FK91; 05FK092	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 1T/kit x25 each 25T/kit 1T/kit x 25 each

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2015	HCV EIA	INNO-LIA HCV Score	80538	CE-mark	Fujirebio Europe NV	Zwijnaarde, Belgium	20T/kit
2015	HIV EIA	DS-EIA-HIV-AGAB-SCREEN	I-1654/1.2; I-1652/1.2; I-1656/1.2	CE-mark	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/1 plate; 192T/2 plates; 480 T/5 plates
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf/PAN) COMBO	multi kit (product codes: RMRM-02571; RMRM-02571CB; RMRM-02571RB; RMRM-02571RI; RMRM-05071; RMRM-05071CB; RMRM-05071RB and RMRM-05071RI) single kit (product codes: RMRU-02571; RMRU-02571CB; RMRU-02571RB; RMRU-02571RI; RMRU-04071; RMRU-04071CB; RMRU-04071RB and RMRU-04071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit. 25T/kit; 40T/kit.
2015	Malaria RDT	**CareStart Malaria HRP2 (Pf)	multi kit (product codes: RMOM-02571; RMOM-02571CB; RMOM-02571RB; RMOM-02571RI; RMOM-05071; RMOM-05071CB; RMOM-05071RB and RMOM-05071RI) single kit (product codes: RMOU-02571; RMOU-02571CB; RMOU-02571RB; RMOU-02571RI; RMOU-05071; RMOU-05071CB; RMOU-05071RB and RMOU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit; 25T/kit; 40T/kit;
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf/Pv) COMBO	multi kit (product codes: RMVM-02571; RMVM-02571CB; RMVM-02571RB; RMVM-02571RI; RMVM-05071; RMVM-05071CB; RMVM-05071RB and RMVM-05071RI) single kit (product codes: RMVU-02571; RMVU-02571CB; RMVU-02571RB; RMVU-02571RI; RMVU-05071; RMVU-05071CB; RMVU-05071RB and RMVU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf)	multi kit (product codes: RMPM-02571; RMPM-02571CB; RMPM-02571RB; RMPM-02571RI; RMPM-05071; RMPM-05071CB; RMPM-05071RB and RMPM-05071RI) single kit (product codes: RMPU-02571; RMPU-02571CB; RMPU-02571RB; RMPU-02571RI; RMPU-05071; RMPU-05071CB; RMPU-05071RB and RMPU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit
2015	Malaria RDT	**CareStart Malaria pLDH (PAN)	multi kit (product codes: RMNM-02571; RMNM-02571CB; RMNM-02571RB; RMNM-02571RI; RMNM-05071; RMNM-05071CB; RMNM-05071RB and RMNM-05071RI) single kit (product codes: RMNU-02571; RMNU-02571CB; RMNU-02571RB; RMNU-02571RI; RMNU-05071; RMNU-05071CB; RMNU-05071RB and RMNU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit
2015	HIV Confirmatory Assay	INNO-Lia HIV I/II Score	80540	CE-mark	Fujirebio Europe NV	Ghent, Belgium	20T/kit

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2015	HIV EIA	Murex HIV Ag/Ab Combination	7G79-09 (GE41, 96 wells); and 7G79-11 (GE42, 480 wells)	CE-mark	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit
2014	HIV NAT	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	06693083190; 03051315001; 03279332001; 03587797190; 06989861190; 05807875001; 03516440001; and 28127387001	CE-mark	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	48T/kit
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-mark	Roche Diagnostics GmbH	Mannheim, Germany	48T/kit
2014	HIV RDT	SURE CHECK HIV 1/2 Assay	HIV201 (60-9527-0),	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	25T/kit
2014	HBsAg EIA	Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3	9F80-01; 9F80-05; 2G27-01	CE-mark	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit 50T/kit
2014	Malaria RDT	ParaHIT f Ver. 1.0 Rapid Test for P.falciparum Malaria Device	55IC104-10; 55IC104-25; 55IC104-50	CE-mark	ARKRAY Healthcare Pvt. Ltd.	Sachin (Surat), India	10T/kit; 25T/kit; 50T/kit
2014	CD4 Technologies	# BD FACSPresto Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and BD FACSPresto Cartridges Kit	651000; 657681; 655495	CE-mark	Becton, Dickinson and Company, BD Biosciences	San Jose, California, USA	651000: instrument 657681: cartridge (100/box) 655495: pipette (100/box)
2014	HIV RDT	# ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402WI, IHI-T402WA, IHI-T402WG, IHI-T402WB, IHI-T402WD, IHI-T402WE, IHI-T402WF	RoW	ABON Biopharm (Hangzhou) Co. Ltd.	Hangzhou, PR China	40T/kit; 40T/kit; 40T/kit; 40T/kit; 10T/kit; 40T/kit 10T/kit
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 materials; 48T/kit without support material; 48T/kit with support materials; 48T/kit with pipettes but no lancet, no alcohol
2013	Malaria RDT	Bioline Malaria Ag P.f/Pan	05FK60; 05FK61; 05FK62; 05FK63; 05FK67	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 25x1T/kit; 1T/kit; 25T/kit; 30T/kit
2013	HIV NAT	Abbott RealTime HIV-1 Qualitative (Manual)	4N66-90; 4N66-80; 6K12-24; 9K15-01; 4N66-01; and 4N66-66 (optional)	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack
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-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack
2013	HIV RDT	Bioline HIV-1/2 3.0	03FK10; 03FK16; 03FK17	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit; 25T/kit; 25T/kit

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2013	HIV EIA	Genscreen ULTRA HIV Ag-Ab	72386; and 72388	CE-mark	Bio-Rad	Marnes La Coquette, France	96T/kit; 480T/kit
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
2012	CD4 Technologies	Pima CD4 Test	260100025 and 260300003; 260100100; and 260300003	CE-mark	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1, D-07743 Jena, Germany	25 cartridges/kit and instrument; 100 cartridges/kit and instrument
2012	CD4 Technologies	# BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (<i>Absolute CD4+, CD8+, and CD3+ Counts</i>)	337858; 340166; 340167	CE-mark	Becton, Dickinson and Company, BD Biosciences	San Jose, CA, USA	337858: instrument system 340166: 25T /kit 340167: 50T/kit
2012	CD4 Technologies	# BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount CD4 Reagent Kit (<i>Absolute and Percentage CD4+ Counts</i>)	337858; 340166; 339010	CE-mark	Becton, Dickinson and Company, BD Biosciences	San Jose, CA, USA and Cayey, Puerto Rico	337858: instrument system 340166: 25T/kit 339010: 50T/kit
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-mark	Roche Diagnostics GmbH	Mannheim, Germany	05212294190: 48T/kit 03587797190: 5.1 liters
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-mark	Roche Molecular Systems, Inc.	Branchburg, NJ, USA	05212294190: 48T/kit 03587797190: 5.1 liters
2012	HIV RDT	HIV 1/2 STAT-PAK	HIV101	RoW	Chembio Diagnostic Systems Inc.	Site 1: Chembio Diagnostic Systems, Inc. (3661 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, UEP, 47600, Subang Jaya, Selangor, Malaysia	20T/kit
2011	HIV NAT	NucliSENS EasyQ HIV-1 v2.0 (Automated)	280140; 280130; 280131; 280132; 280133; 280134; 285056; 200309; and 285033	CE-mark	bioMérieux SA	Marcy L'Etoile, France	280130, 280131, 280132, 280133 and 280134: 4x1L 285033: 48 T/kit
2011	HIV NAT	NucliSENS EasyQ HIV-1 v2.0 (Semi-Automated)	200305; 200293; 200292; 285056; 200309; and 285033	CE-mark	bioMérieux SA	Marcy L'Etoile, France	200293 and 200292: 48T/kit, 285033: 48 T/kit
2011	HIV RDT	# Determine HIV-1/2	7D2342; 7D2343; 7D2343SET and 7D2343SETS.	RoW	Abbott Diagnostics Medical Co., Ltd	Matsudo-shi, Chiba-ken, Japan	20T/kit; 100T/kit; 100T/kit; 100T/kit

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2011	HIV NAT	Abbott RealTime HIV-1 (Manual)	2G31 (2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit
2011	HIV NAT	# Abbott RealTime HIV-1 (m 2000sp)	2G31 (2G31-90 or 2G31-010, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; 04J71-93; and 9K14-02	CE-mark	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); 04J70-24: 96T/kit
2011	HIV NAT	Abbott RealTime HIV-1 (m 24sp)	3N06-01, 2G31(2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit
2010	Malaria RDT	Bioline Malaria Ag P.f	05FK50; 05FK51; 05FK52; 05FK53	CE-mark	Abbott Diagnostics Korea Inc	Giheung-ku, Republic of Korea	25T/kit; 25T/kit; 1T/kit x 25 each; 1T/kit x 25 each.

** 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
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	HBsAg 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	HBsAg 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	I05FRC100, I05FRC60, I05FRC30, and I05FRC05	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	OPIH035 and OPIH055	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	55IC103-10, 55IC103-25 and 55IC103-50	Arkay Healthcare Private Limited	Failure to meet product testing acceptance criteria.

End of document