World Health Organization

WHO list of prequalified in vitro diagnostic products

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

Last update: 22 February 2022

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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 6800/8800 Systems)	6997732190	CE-mark	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit
2021	Syphilis RDT	First Response Syphilis Anti-TP Card Test	PI08FRC25, PI08FRC50 PI08FRC100	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
2020	HIV NAT	cobas HIV-1 Quantitative nucleic acid test for use on the cobas 6800/8800 Systems	07000995190	CE-mark	Roche Diagnostics GmbH,	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit
2020	HIV RDT	MERISCREEN HIV 1-2 WB	HVWRPD-01 HVWRPD-02	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
2020	Malaria RDT	Paracheck Pf - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	302030005, 302030010, 302030025, 302030100.	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	5 T/kit 10 T/kit 25 T/kit 100 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	OD376	CE-mark	Omega Diagnostics Ltd	Omega Diagnostics 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	503030010; 503030025; 503030050; 503030100	CE-mark	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.	M46-47, Phase III B, Verna, Goa, 403722, India	10 T/kit 25 T/kit 50 T/kit 100 T/kit
2020	Malaria RDT	FalciVax - Rapid test for Malaria Pv/Pf	503010010; 503010025; 503010050; 503010100	CE-mark	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.	M46-47, Phase III B, Verna, Goa, 403722, India	10 T/kit 25 T/kit 50 T/kit 100 T/kit

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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
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 RealTi*me* 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 RealTi*me* 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

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2019	HBsAg RDT	*Determine HBsAg 2	7D2942; 7D2943; 7D2943 SET	CE-mark	Alere 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 Pvty. Ltd	**Site 1:** Atomo Diagnostics Pty Ltd atLevel 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
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-MALADX-004-025	RoW	Advy Chemical Pvt Ltd.,	Plot No.A-334,336,338 & A-337 & 339 Road no. 25 & 26, Wagle industial Estate Thane 400 604 India	25 T/kit
2019	Malaria RDT	*NxTek Eliminate Malaria Pf	05FK140	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
			05FK141				25T/Kit
			05FK142				1T/kit x 25 each
			05FK143				1T/kit x 25 each
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
		First Response Malaria Antigen P	PI13FRC25s			**site 1:** A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India;	25 × single kit
			PI13FRC10s				10 × single kit

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2018	Malaria RDT	First Response Malaria Antigen P. *falciparum* (HRP2) Card Test	PI13FRC25	RoW	Premier Medical Corporation Limited	India; **site 2:** 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	25 × multi kit
			PI13FRC30				30 × multi kit
2018	Malaria RDT	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC10s	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 kit
			PI16FRC25s				25 × single kit
			PI16FRC25				25 × multi kit
			PI16FRC30				30 × multi kit
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	PI19FRC10s	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
			PI19FRC25s				25 × single test
			PI19FRC30				30 × multi test
			PI19FRC25				25 × multi test
2018	Malaria RDT	*Bioline Malaria Ag P.f/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 , W006-P0052	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; 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	CD4 Technologies	*CyFlow Counter System with CD4 easy count kit and CD4% easy count kit	CY-S-3022; 05-8401; and 05-8405	CE-marked	Sysmex 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

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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	Virological Technologies	Xpert HPV	GXHPV-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit
2017	Virological Technologies	*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 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	50T/kit; 250T/kit; 110T/kit
2017	Virological Technologies	*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
2016	HIV NAT	*m-PIMA HIV-1/2 Detect	270110050; 270110010; 270300001	CE-mark	Alere Technologies GmbH	Jena, Germany	50 cartridges/kit 50 cartridges/kit Instrument

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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	Nizhniy 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 ELISA	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-18S10EL; WJ-18S50EL; WJ-18S10; WJ-18S50; WJ-18S10E;	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; 50 T/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	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	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

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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
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	Nizhniy 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)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit;
			single kit (product codes: RMRU-02571; RMRU-02571CB; RMRU-02571RB; RMRU-02571RI; RMRU-04071; RMRU-04071CB; RMRU-04071RB and RMRU-04071RI)				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)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit;
			single kit (product codes: RMOU-02571; RMOU-02571CB; RMOU-02571RB; RMOU-02571RI; RMOU-05071; RMOU-05071CB; RMOU-05071RB and RMOU-05071RI)				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)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit
			single kit (product codes: RMVU-02571; RMVU-02571CB; RMVU-02571RB; RMVU-02571RI; RMVU-05071; RMVU-05071CB; RMVU-05071RB and RMVU-05071RI)				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)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit

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			single kit (product codes: RMPU-02571; RMPU-02571CB; RMPU-02571RB; RMPU-02571RI; RMPU-05071; RMPU-05071CB; RMPU-05071RB and RMPU-05071RI)				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)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit
			single kit (product codes: RMNU-02571; RMNU-02571CB; RMNU-02571RB; RMNU-02571RI; RMNU-05071; RMNU-05071CB; RMNU-05071RB and RMNU-05071RI)				25T/kit; 40T/kit
2015	HIV Confirmatory Assay	INNO-Lia HIV I/II Score	80540	CE-mark	Fujirebio Europe NV	Ghent, Belgium	20T/kit
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	Virological Technologies	*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	Virological Technologies	*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 Singapore, Singapore	651000: instrument 657681: catridge (100/box) 655495: pipette (100/box)
2014	HIV RDT	*ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402WA; IHI-T0402WG; IHI-T402WB; IHI-T402WC	RoW	ABON Biopharm (Hangzhou) Co. Ltd.	Hangzhou, PR China	40T/kit; 40T/kit; 40T/kit; 5T/kit

World Health Organization

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: 22 February 2022

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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 swabs); 48T/kit with no support materials;
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	Virological Technologies	*Abbott RealT*ime* 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	Virological Technologies	*Abbott RealT*ime* 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
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 *(Absolute CD4+, CD8+, and CD3+ Counts)*	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 *(Absolute and Percentage CD4+ Counts)*	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

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Last update: 22 February 2022

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2012	Virological Technologies	*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	Virological Technologies	*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.	Medford, NY, USA	20T/kit
2011	Virological Technologies	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	Virological Technologies	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
2011	Virological Technologies	*Abbott RealTi*me* 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	Virological Technologies	*Abbott RealTi*me* 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	Virological Technologies	*Abbott RealTi*m* e 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.

***** Public report was amended, please refer to public report for detailed amendments .

****** These products are subject to a WHO Notice of Concern: https://www.who.int/diagnostics_laboratory/procurement/complaints/en/.

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