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Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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	MHLRDP-02	RoW	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
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
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	Genedrive HCV ID Kit	ID-HCV-03	CE-mark	Genedrive Diagnostics Ltd	48 Grafton Street, Manchester, UK	10 T/kit

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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 RealT*ime* 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 RealT*ime* High Risk HPV	02N09-092; and 02N09-080	CE-mark	Abbott GmbH & Co.KG	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	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
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

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2018	Malaria RDT	First Response Malaria Antigen P. *falciparum* (HRP2) Card Test	PI13FRC25s	RoW	Premier Medical Corporation Limited	**site 1:** A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; **site 2:** 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	25 × single kit
			PI13FRC10s				10 × single kit
			PI13FRC25				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-C4P2-F	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	25T/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	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
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	HBsAg RDT	Vikia HBsAg	31124	CE-mark	bioMérieux SA	376 Chemin de l'Orme, Marcy l'Etoile, 69280 France	25 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

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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	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	RoW	OraSure Technologies, Inc.	Bethlehem, USA	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	Alere HIV Combo	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

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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
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 and **site 2**: Petchabun, 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; B1255/1.2; 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	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	10T/kit w/accessories; 10T/kit; 25T/kit; 50T/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)

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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
2013	HIV RDT	VIKIA HIV 1/2	31112	CE-mark	bioMérieux SA	Marcy L'Etoile, France	25T/kit
2013	HIV RDT	*INSTI HIV-1/HIV-2 Antibody Test	90-1013; 90-1010; 90-1022; 90-1021	RoW	BioLytical Laboratories, Inc.	Richmond, British Columbia, Canada	24T/kit; 24T/kit with support materials; 48T/kit; 48T/kit with 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 RealTi*me* 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 RealTi*me* 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

WHO list of prequalified in vitro diagnostic products

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Last update: 21 May 2021

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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
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	Alere Determine HIV-1/2	7D2342; 7D2343; and 7D2343SET	RoW	Alere Medical Co. Ltd.	Matsudo-shi, Chiba-ken, Japan	20T/kit; 100T/kit; 100T/kit
2011	HIV RDT	HIV 1/2 STAT-PAK Dipstick	HIV303	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	1Tx30/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

World Health Organization

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Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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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