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WHO list of prequalified in vitro diagnostic products

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Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2018	Malaria RDT	First Response® Malaria Antigen P. *falciparum* (HRP2) Card Test	PI13FRC25s	rest-of-world	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	rest-of-world	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	rest-of-world	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	SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120 and 05FK123	CE-mark	Standard Diagnostics, 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	rest-of-world	bioLytical Laboratories Inc.	Richmond, British Columbia, Canada	1T/kit
2018	HIV RDT	One Step HIV1/2 Whole Blood/Serum/Plasma Test	W006-C4P2 and W006-C4P2-F	rest-of-world	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	rest-of-world	Meril Diagnostics Pvt. Ltd.	D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India	30T/kit

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2018	CD4 Technologies	CyFlow® Counter System with CD4 easy count kit and CD4% easy count kit	CY-S-3022, 05-8401, 05-8405	CE-marked	Sysmex Partec GmbH	Arndtstr. 11a-b, 02826 Görlitz, Germany; and 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	QIAGEN Sciences, Germantown, 20874, United States QIAGEN Shenzhen Co., Shenzhen China	96 T/kit
2018	CD4 Technologies	Muse Auto CD4/CD4% kit	MCA100101, MCA500101, MCA1XK101	CE-mark	EMD Millipore Corporation	Temecula, California 92590, USA	100 T/kit; 500 T/kit; 1000 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	SD BIOLINE HBsAg WB	01FK10W	RoW	Standard Diagnostics, 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
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

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2017	HIV Confirmatory Assay	Geenius™ HIV 1/2 Confirmatory Assay with Geenius™ HIV1/2 Confirmatory Controls	72460, 72329	CE-mark	Bio-Rad	Marnes-La-Coquette, France	20T/kit
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1001-0270, 1001-0274	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, A-GOLD-01	RoW	Shanghai Kehua Bio-engineering Co., Ltd	Shanghai, PR China	50T/kit
2016	HCV RDT	SD BIOLINE HCV	02FK10	RoW	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	30T/kit
2016	HBsAg EIA	bioelisa HBsAg 3.0	3000-1158, 3000-1159	CE-mark	Biokit S.A.	Llicà d`Amunt, Spain	96T/kit; 480T/kit
2016	HIV RDT	First Response® HIV 1-2-0 Card Test	I05FRC100, I05FRC60, I05FRC30, I05FRC05	RoW	Premier Medical Corporation	Nani Daman, Daman, India and Sarigam, Gujarat, India	100T/kit; 60T/kit; 30T/kit; 5T/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
2016	HIV NAT	Alere™ q HIV-1/2 Detect	270110050, 270110010, 270300001	CE-mark	Alere Technologies GmbH	Jena, Germany	10 cartridges/kit and instrument; 50 cartridges/kit and 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, 5x4-0012 5x-0014 and 5x-0015	RoW	OraSure Technologies, Inc.	Bethlehem, USA and Petchabun, Thailand	100T/kit; 500T/kit

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2016	HBsAg EIA	DS-EIA-HBsAg-0,01	B-1254, B-1252, B-1255, B-1256, B-231	CE-mark	RPC Diagnostics Systems	Nizhniy Novgorod, Russia	96T/kit; 192T/kit; 480T/kit; 96T or 48T (if confirmation)/kit 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, B23502	CE-mark	Beckman Coulter Life Sciences	Miami, FL, USA (instrument site) and Hialeah, FL, USA (reagent site)	50T/kit
2015	HIV/Syp RDT	Alere™ HIV/Syphilis Duo	06FK30, 06FK35	RoW	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	25T/kit
2015	Malaria RDT	SD BIOLINE Malaria Ag P.f/P.v	05FK80, 05FK81, 05FK82, 05FK83, 05FK86, 05FK87	CE-mark	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	25T/kit; 25X1T/kit
2015	Malaria RDT	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90, 05FKFK93, 05FK91, 05FK092	CE-mark	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	25T/kit; 25X1T/kit
2015	HCV EIA	INNO-LIA HCV Score	80538	CE-mark	Fujirebio Europe NV	Zwijnaarde, Belgium	20T/kit

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2015	HIV EIA	DS-EIA-HIV-AGAB-SCREEN	I-1654, I-1652, I-1656	CE-mark	RPC Diagnostics Systems	Nizhniy Novgorod, Russia	96T/1 plate; 192T/2 plates; 480 T/5 plates
2015	HCV EIA	Murex anti-HCV (version 4.0)	7F51-01, 7F51-02	RoW	DiaSorin South Africa (Pty) Ltd.	Kyalami, South Africa	96T/kit 480T/kit
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;

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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
			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	**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

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2015	Malaria RDT	(PAN)	**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; 40T/kit
2015	HIV Confirmatory Assay	INNO-Lia HIV I/II Score	80540	CE-mark	Fujirebio Europe NV	Ghent, Belgium	20T/kit
2015	HCV EIA	Bioelisa HCV 4.0	3000-1115, 3000-1116	CE-mark	Biokit S.A.	Barcelona, Spain	96T/kit; 480T/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
2015	HIV EIA	Bioelisa HIV 1+2 Ag/Ab	3000-1172, 3000-1173	CE-mark	Biokit S.A.	Barcelona, Spain	96T/kit; 480T/kit
2015	Malaria RDT	First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25, I13FRC30	RoW	Premier Medical Corporation	Nani Daman and Sarigam, India	25T/kit; 30T/kit
2014	Virological Technologies	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	06693083190, 03051315001, 03279332001, 03587797190, 06989861190, 05807875001, 03516440001, 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)	06693083 190, 03587797190, 06989861190, 03051315001, 03121453001, 28127387001, 05807875001, 03516440001	CE-mark	Roche Diagnostics GmbH	Mannheim, Germany	48T/kit
2014	HIV RDT	SURE CHECK® HIV 1/2 Assay	HIV201	CE-mark	Chembio Diagnostic Systems Inc.	Medford, NY, USA	25T/kit

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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
2014	Malaria RDT	ParaHIT f Ver. 1.0 Rapid Test for P.falciparum Malaria Device	55IC104-10, 55IC104-25 and, 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) and 655495: pipette (100/box)
2014	HIV RDT	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402WG, IHI-T0402WA	RoW	ABON Biopharm (Hangzhou) Co. Ltd.	Hangzhou, PR China	40T/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	SD BIOLINE Malaria Ag P.f/Pan SD BIOLINE Malaria Ag P.f/Pan (POCT)	05FK60, 05FK61, 05FK62, 05FK63, 05FK67	CE-mark	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	25T/kit; 25x1T/kit; 1T/kit; 25T/kit; 30T/kit

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2013	Virological Technologies	Abbott RealTi*m* e HIV-1 Qualitative (Manual)	4N66-90, 4N66-80, 6K12-24, 9K15-01, 4N66-01, 4N66-66 (optional)	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack
2013	Virological Technologies	Abbott RealTi*m* e HIV-1 Qualitative (*m* 2000sp)	4N66-90, 9K14-02, 9K15-01, 4N66-80, 4N66-01, 6K12-24, 4N66-66 (optional)	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack
2013	HIV RDT	SD BIOLINE HIV-1/2 3.0	03FK16, 03FK10 and 03FK17	RoW	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	25T/kit; 30T/kit
2013	HIV EIA	Genscreen™ ULTRA HIV Ag-Ab	72386, 72388	CE-mark	Bio-Rad	Marnes La Coquette, France	96T/kit; 480T/kit
2012	HIV RDT	Uni-Gold™ HIV	1206502, 1206502N, 1206502E, 1206502N-100	RoW	Trinity Biotech Manufacturing Ltd.	Bray, Ireland	20T/kit; 100T/kit
2012	CD4 Technologies	Pima CD4 Test	260100025 and 260300003; 260100100 and 260300003	CE-mark	Alere Technologies GmbH	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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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, 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, 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, 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 RealTime HIV-1 (Manual)	2G31 (2G31-90, 2G31-80, 2G31-70), 2G31-66, 1L68-09, 9K15-01, 04J70-24, 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

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2011	Virological Technologies	Abbott RealTi*m* e HIV-1 (*m* 2000sp)	2G31 (2G31-90 or 2G31-010, 2G31-80, 2G31-70), 2G31-66, 1L68-09, 9K15-01, 04J70-24, 04J71-93, 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, 04J71-93	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T); 2 G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit
2010	Malaria RDT	SD BIOLINE Malaria Ag P.f SD BIOLINE Malaria Ag P.f. (POCT)	05FK50, 05FK51, 05FK52, 05FK53	CE-mark	Standard Diagnostics, Inc.	Giheung-ku, Republic of Korea	25T/kit, 25x1T/kit 1T/kit

* Product originally prequalified in 2010 and amended in 2016 to include an additional product code.

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