

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: 18 September 2019

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2019	HIV RDT	First Response HIV 1-2.O Card test (Version 2.0)	PI05FRC25 PI05FRC30 PI05FRC50 PI05FRC60 PI05FRC100	RoW	Premier Medical Corporation Private Limited	A1-302, GIDC, Sarigam, India	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	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 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 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
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

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2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40 ITPW02152-TC25 ITPW02153-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	HCV RDT	Rapid Anti-HCV Test	ITPW01152-TC40; ITPW01152-TC25; and 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 industrial Estate Thane 400 604 India	25 T/kit
2019	Malaria RDT	Alere Malaria Ag P.f	05FK140	CE-mark	Standard Diagnostics, 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	Alere Technologies GmbH	Loebstedter Str. 103-105, Jena, Thuringia, 07749, Germany	50 cartridges/kit
2018	Malaria RDT	First Response® Malaria Antigen <i>P. falciparum</i> (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

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			PI13FRC30			Kachigam, Nani Daman, Daman 396215, India	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	SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120; 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	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	RoW	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	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	<i>care</i> 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	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

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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; 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; A-GOLD-01	RoW	Shanghai Kehua Bio-engineering Co., Ltd	Shanghai, PR China	50T/kit
2016	HCV RDT	*SD BIOLINE HCV	02FK10 02FK16 02FK17	RoW	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	30T/kit 25T/kit 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	site 1: Nani Daman, Daman, India and site 2: 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

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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; 5x-0015	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA and site 2: Petchabun, Thailand	100T/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 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 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	*SD BIOLINE HIV/Syphilis Duo	06FK30 06FK35	RoW	Standard Diagnostics, Inc.	Giheung-gu, Republic of Korea	25T/kit 25T/kit

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2015	Malaria RDT	SD BIOLINE Malaria Ag P.f/P.v	05FK80; 05FK81; 05FK82; 05FK83; 05FK86 and 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; 05FK93; 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
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)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/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;
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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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
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
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

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2014	HIV RDT	SURE CHECK® HIV 1/2 Assay	HIV201	CE-mark	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
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: cartridge (100/box) and 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
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

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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
2013	Virological Technologies	Abbott RealTime 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 RealTime 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; 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; 1206502-C; 1206502E-C; 1206502N-100 and 1206502-100	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 FACSCoount Instrument System with FACSCoount Control Kit and BD FACSCoount 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

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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	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; 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

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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 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 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	Virological Technologies	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	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 and public report was amended. See public report for detailed amendments .

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