

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: 11 February 2020

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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	1927/kit 4807/kit
2017	HbSAg RDT	SD BIOLINE HbSAg WB	01FK10W	Row	Standard Diagnostics, Inc.	Giljeung-gu, Republic of Korea	307/kit
2017	HIV RDT	Genie™ Fast HIV 1/2	72327; 72347; 72330	CE-mark	Bio-Rad	Marne La Coquette, France	257/kit 507/kit 507/kit
2017	Virological Technologies	Xpert HPV	GKHPV-CE-10	CE-mark	Cepheid AB	Solna, Sweden	107/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	1007/kit
2017	HIV RDT for self- testing	*OraQuick HIV Self-Test	5X4-1000; 5X4-1001; 5X4-2001	Row	OraSure Technologies, Inc.	Bethlehem, USA	507/kit; 2507/kit; 1107/kit
2017	Virological Technologies	*Xpert® HIV-1 Viral Load	GKHN-VL-CE-10	CE-mark	Cepheid AB	Solna, Sweden	107/kit
2017	HCV NAT	*Xpert® HCV Viral Load	GKHC-VL-CE-10	CE-mark	Cepheid AB	Solna, Sweden	107/kit
2017	HIV Confirmatory Assay	Genieus™ HIV 1/2 Confirmatory Assay with Genieus™ HIV1/2 Confirmatory Controls	72460; and 72329	CE-mark	Bio-Rad	Marnes-La-Coquette, France	207/kit
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1001-0270; 001-0274	CE-mark	OraSure Technologies, Inc.	Bethlehem, USA	257/kit; 1007/kit

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2016	HIV RDT	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	R-401-50-C-2; KH-R-Q2; and 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.	Gilneung-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.	Llida d'Amunt, Spain	96T/kit; 480T/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	GKHIV-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
2016	HIV RDT	DPP® HIV 1/2 Assay	65-9506-0	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	20T/kit
2016	HIV RDT	*OracQuick 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: Petchaburi, 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	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 Biot 2.2	11030-018; 11030-036	CE-mark	MP Biomedicals Asia Pacific Pte.Ltd.	Singapore, Singapore	18T/kit; 36T/kit