

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: 7 April 2022

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2016	HIV RDT	*Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	WJ-181D; WJ-181DE; WJ-185D; WJ-185DE; WJ-181DEL; WJ-185DEL; WJ-185DEL; WJ-185DEL; WJ-185DEL; WJ-185D; WJ-185D; WJ-1851DE; WJ-1855DE	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	107/kit; 107/kit; 507/kit; 507/kit; 10 T/kit; 50 T/kit; 10 T/kit; 50 T/kit; 10 T/kit; 50 T/kit; 10 T/kit; 50 T/kit; 10 T/kit; 50 T/kit;
2015	CD4 Technologies	Aquios CL flow cytometer	B30166; B39101; B39102; B25697; B25698; B23536; B23538; B23539; 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)	507/kit
2015	HIV/Syp RDT	*Bioline HIV/Syphilis Duo	06FK30; 06FK35; 06FK37	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	257/kit; 257/kit; 257/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	257/kit; 257/kit; 117/kit x25 each 117/kit x25 each 107/kit 257/kit
2015	Malaria RDT	*Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90; 05FK93; 05FK91; 05FK92	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	257/kit; 117/kit x25 each 257/kit 117/kit x 25 each
2015	HCV EIA	INNO-LIA HCV Score	80538	CE-mark	Fujirebio Europe NV	Zwijnaarde, Belgium	207/kit
2015	HIV EIA	*DS-EIA-HIV-AGAB-SCREEN	I-1654/I.2; I-1652/I.2; I-1656/I.2	CE-mark	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/1 plate; 192T/2 plates; 480 T/5 plates