

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: 20 October 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
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-MAL-ADX-004-001, 00-DKM-RK-MAL-ADX-004-025, 00-DKM-RK-MAL-ADX-004-010, and 00-DKM-RK-MAL-ADX-004-050	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	1 T/kit, 10 T/kit, 25 T/kit, 50 T/kit
2019	Malaria RDT	# NxTek Eliminate Malaria Pf and and NxTek Malaria Pf	05FK140; 05FK141; 05FK142; 05FK143 05FK144	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; 25T/Kit; 1T/kit x 25 each; 1T/kit x 25 each 25T/Kit
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
2018	Malaria RDT	First Response Malaria Antigen P. <i>falciparum</i> (HRP2) Card Test	PI13FRC25s; PI13FRC10s; PI13FRC25; PI13FRC30	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 x single kit; 10 x single kit; 25 x multi kit; 30 x multi kit
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	PI19FRC10s; PI19FRC25s; PI19FRC30; PI19FRC25	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 x single test; 30 x multi test; 25 x multi test
2018	Malaria RDT	Bioline Malaria Ag 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-P0045, W006-P0046, W006-P0047, W006-P0048, W006-C4P2-F, W006-P0049, W006-P0050, W006-P0051.	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	25T/kit; 25T/kit; 25T/kit; 25T/kit; 25T/kit; 40T/kit; 40T/kit; 40T/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; MFLRPD-05	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; 10 T/kit.
2018	Malaria RDT	First Response Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC10s PI16FRC25s PI16FRC25 PI16FRC30	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 x single kit 25 x single kit 25 x multi kit 30 x multi kit