



WHO list of prequalified in vitro diagnostic products

Raw list of the world. Regulatory version applied to products not approved by antigen/antibody NMs or not regulated
Last update: 29 August 2020

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Link to access public report
2019	HCV EIA	ARCHITECT HCV Ag assay	644729 (647-1); 647432 and 649041	CE mark	Denka Seiken Co., LTD, Agemada Factory	Street 1399-1, Agemada, Kagoshima, Japan	300 T/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	HW RDT for self-testing	#MyJan HIV Self-Test	AW1001-03; AW1001-04; AW1001-05; AW1001-06; AW1001-07-09	ROW	Alamo Diagnostics Pvt. Ltd	Site # Alamo Diagnostics Pvt. Ltd. Gate No. 2, 70/232 Paramatta Road, New Delhi, India Site # Line of Low Laboratories (L3) at Unit 1, 8, 2, Greenview Place, Cape Town, Crescent, Clarendon Technology Park, Muizenberg, 7825, South Africa	1 T/AR; 1 T/AR; 1 T/AR; 25 T/AR 50 T/AR 60 T/AR 100 T/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	HW/Type RDT	#First Response HIV-1/2 Syphilis Combo Card Test	IPW0213-TC-01; IPW0213-TC-02; IPW0213-TC-03; IPW0213-TC-04	ROW	Premier Medical Corporation Private Limited	Saigam, Gujarat, India	25 T/AR 50 T/AR 60 T/AR 100 T/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	HW RDT	ONE STEP Anti-HIV (1&2) Test	IPW0213-TC-05; IPW0213-TC-06; IPW0213-TC-07A	ROW	INTC PRODUCTS, INC	308, Wengshao Rd., Anying IND, ABEA, Hechang, Xiamen, 361022, China	40 T/AR 25 T/AR 50 T/AR 60 T/AR 40 T/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	HOW RDT	RapidSave-HCV Test	IPW0115-TC-01; IPW0115-TC-02; IPW0115-TC-03	ROW	INTC PRODUCTS, INC	308, Wengshao Rd., Anying IND, ABEA, Hechang, Xiamen, 361022, China	40 T/AR 25 T/AR 50 T/AR 60 T/AR 40 T/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	Malaria RDT	Ardx Malaria Pf Rapid Malaria Ag Detection Test	DD-DMM-AR-MAL-ARX-004-025	ROW	Athy Chemical Pvt. Ltd.,	Pkt No. A-334, 334/338 & A-337 A, 339 Thane, Maharashtra, India Thane 400104	25 T/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	Malaria RDT	#MAtok Eliminate Malaria Pf and and INtAct Malaria Pf	DFPK14-01; DFPK14-02; DFPK14-03; DFPK14-04	CE mark	Abbott Diagnostics Korea Inc	Site # 1-46, Haejeon-ro 15 Beongri, Gyeongju-si, Gyeongju-do 71039, Republic of Korea Site # 25, Beomdeok-ro, Gyeongju-si, Gyeongju-do 71039, Republic of Korea	125 P/AR; 17 P/AR x 25 each; 17 P/AR x 25 each 257 P/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2019	HW NAT	#m-PMAS HIV-1/2 VL	27015-V500	ROW	Abbott Rapid Diagnostics (India) GmbH	Oringweg 1, D-07749 Jena, Germany	50 cartridges/vial	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2018	Malaria RDT	First Response Malaria Antigen P2 (Algorithms) Card Test	P13PRC25-01; P13PRC25-02; P13PRC25-03; P13PRC25-04	ROW	Premier Medical Corporation Limited	Site # 1, A1-302, GDC, Sangam 390155, Vadod, Gujarat, India Site # 23, 31A, Shree Gresham Industrial Estate, Kachigam, Navi Mumbai, District 400615, India	25 x single kit; 10 x single kit; 25 x multi kit; 25 x multi kit	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2018	Malaria RDT	First Response Malaria Ag. Pf / P.v. Card Test	P13PRC25-05; P13PRC25-06; P13PRC25-07; P13PRC25-08	ROW	Premier Medical Corporation Limited	Site # 1, A1-302, GDC, Sangam 390155, Vadod, Gujarat, India Site # 23, 31A, Shree Gresham Industrial Estate, Kachigam, Navi Mumbai 400615, India	25 x single test; 10 x multi test; 25 x multi test	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2018	Malaria RDT	Beline Malaria Ag. P1/P2/Pv	DFPK12-01; DFPK12-02	CE mark	Abbott Diagnostics Korea Inc	65, Borahga-ri, Gyeongju-si, Gyeongju-do 71039, Gyeongju-do, South Korea	257 P/AR; 17 P/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2018	HW RDT for self-testing	INSTIHV Self-Test	901-071	ROW	biological laboratorie inc.	Richmond, British Columbia, Canada	17 P/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2018	HW RDT	One Step HIV-1/2 Syphilis Rapid Serum (Rapid) Test	W005-CAR2; W005-P004; W005-P005; W005-P006; W005-P007; W005-P008; W005-P009; W005-CAR1; W005-CAR2; W005-P005; W005-P006; W005-P007; W005-P008; W005-P009	ROW	Guangzhou Wonbio Biotech Co., Ltd	Guoshikou Road, Foshan City, Jiangnan District, Guangzhou, 510665, Republic of China	257 P/AR; 257 P/AR; 257 P/AR; 407 P/AR; 407 P/AR; 407 P/AR; 407 P/AR; 407 P/AR; 407 P/AR;	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041
2018	Malaria RDT	One Step test for Malaria P1/Pv Ag MIBSD-06 MIBSD-06 MIBSD-06	MIBSD-02; MIBSD-03; MIBSD-04; MIBSD-05; MIBSD-06	CE marked	Mel Diagnostics Pvt. Ltd.	D-10, Meeri Park, Survey No. 1157/B & 17A/2, Maitland Wing, Chiba, Vno 398191, Gujarat, India	307 P/AR; 257 P/AR; 257 P/AR; 37 P/AR	https://extranet.who.int/inform/public-report/public-report.html?reportid=64729&reportid=647432&reportid=649041