



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	ARCHTECT HCV Ag assay	644729; 647111; 647402 and 648901	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?product=644729&date=03/07/2020
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 street 2, 201/202 Paramatta Road, Sydney, Australia Site # Lane of New Labaratories B11 at Unit 1, 8, 2, Greenview Place, Cape Town, Capetown, Capetown Technology Park, Maitlandberg, TMS, 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?product=AW1001-03&date=03/03/2020
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?product=IPW0213-TC-01&date=03/07/2020
2019	HW RDT	ONE STEP Anti-HIV (1&2) Test	IPW0213-TC-05; IPW0213-TC-06; IPW0213-TC-07A	ROW	INTEC PRODUCTS, INC	308, Wengshao Rd., Anyang IND, ABEA, Heilong, Xiamen, 380022, 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?product=IPW0213-TC-05&date=03/07/2020
2019	HW RDT	RapidJave-HCV Test	IPW0115-TC-01; IPW0115-TC-02; IPW0115-TC-03	ROW	INTEC PRODUCTS, INC	308, Wengshao Rd., Anyang IND, ABEA, Heilong, Xiamen, 380022, 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?product=IPW0115-TC-01&date=03/07/2020
2019	Malaria RDT	Auto Malaria Pf Rapid Malaria Ag Detection Test	DD-DMM-M-AVAL-008-008-025	ROW	Amy Chemical Pvt. Ltd.,	Pkt No. A-334, 334/338 & A-337 A, 339 Phase II, 70, Wajga Industrial Estate Thane-400104, India	25 T/AR	https://extranet.who.int/inform/public-report/public-report.html?product=DD-DMM-M-AVAL-008-008-025&date=03/03/2020
2019	Malaria RDT	# NAT-ek Eliminate Malaria Pf and and NAT-ek Malaria Pf	DFPK14-01; DFPK14-02; DFPK14-03; DFPK14-04	CE mark	Abbott Diagnostics Korea Inc	Site # 1-46, Haejeon-ro 15 Beongni, Gyeongju-si, Gyeongju-do 71039, Republic of Korea Site # 25, Beukjeok-ro, Gyeongju-si, Gyeongju-do 71039, Republic of Korea	125 P/AR; 17 P/AR, 25 each; 17 P/AR, 25 each	https://extranet.who.int/inform/public-report/public-report.html?product=DFPK14-01&date=03/03/2020
2019	HW NAT	# m-RIMA HIV-1/2 V/L	27015-V500	ROW	Abbott Rapid Diagnostics (India) GmbH	Ohringstr. 1, D-07749 Jena, Germany	50 cartridges/kit	https://extranet.who.int/inform/public-report/public-report.html?product=27015-V500&date=03/03/2020
2018	Malaria RDT	First Response Malaria Antigen P/Ag (Rapid) Card Test	P13PRC25-01; P13PRC25-02; P13PRC25-03; P13PRC25-04	ROW	Premier Medical Corporation Limited	Site # 1, AT-302, GDC, Sangam 390 150, Vadod, Gujarat, India Site # 23, 23A, Shree Gresham Industrial Estate, Kachigam, Near Daham, Daham 390215, India	25 x single kit; 10 x single kit; 25 x multi kit; 10 x multi kit	https://extranet.who.int/inform/public-report/public-report.html?product=P13PRC25-01&date=03/07/2020
2018	Malaria RDT	First Response Malaria Ag. Pf / P.v. Card Test	P13PRC25-05; P13PRC25-06; P13PRC25-07	ROW	Premier Medical Corporation Limited	Site # 1, AT-302, GDC, Sangam 390 150, Vadod, Gujarat, India Site # 23, 23A, Shree Gresham Industrial Estate, Kachigam, Near Daham 390215, India	25 x single test; 10 x single test; 25 x multi test	https://extranet.who.int/inform/public-report/public-report.html?product=P13PRC25-05&date=03/07/2020
2018	Malaria RDT	Beline Malaria Ag. P/Pv/P.v	DFPK120-01; DFPK123	CE mark	Abbott Diagnostics Korea Inc	65, Beonhwal-ro, Gyeongju-si, Gyeongju-do, Kachigam, 390215, India	25 T/AR; 17 P/AR	https://extranet.who.int/inform/public-report/public-report.html?product=DFPK120-01&date=03/07/2020
2018	HW RDT for self-testing	INSTIHV Self Test	901-071	ROW	biological laboratorie inc.	Richmond, British Columbia, Canada	1 T/AR	https://extranet.who.int/inform/public-report/public-report.html?product=901-071&date=03/03/2020
2018	HW RDT	One Step HIV-1/2 Syphilis Combo Serum (Rapid) Test	W00E-C02; W00E-P005; W00E-P006; W00E-P007; W00E-P008; W00E-C03-1; W00E-C03-2; W00E-P009; W00E-E001	ROW	Guangzhou Wonbio Biotech Co., Ltd	Guoshikun Road, Shuanghe Town, Hengde District, Guangzhou, 510605, Republic of China	25 T/AR; 25 T/AR; 25 T/AR; 40 T/AR; 40 T/AR; 40 T/AR; 60 T/AR;	https://extranet.who.int/inform/public-report/public-report.html?product=W00E-C02&date=03/03/2020
2018	Malaria RDT	One Step test for Malaria P/PPv Ag MIBSD-02; MIBSD-03; MIBSD-04; MIBSD-05	MIBSD-02; MIBSD-03; MIBSD-04; MIBSD-05	CE marked	Mef Diagnostics Pvt. Ltd.	D-1, D-1, Meer Park, Survey No. 1357/B & 17A/2, Mahanagar, Mang. Chav. Vadi 390031, Gujarat, India	30 T/AR; 25 T/AR; 25 T/AR; 3 T/AR.	https://extranet.who.int/inform/public-report/public-report.html?product=MIBSD-02&date=03/03/2020