



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 in at update: 29 August 2023

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	6447-20; 6447-11; 647-02; and R69-01	CE mark	Denka Seiken Co., LTD, Akagasaki Factory	Shirotsu 135-9, Akagasaki, Kagoshima City, Nagasaki, Japan	300 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	HV RDT for self-testing	# Mylan HIV Self Test	ART001-03; ART001-04-01; ART001-04-02; ART001-04-03; ART001-04-04	RoW	Atomo Diagnostics Pvt. Ltd	Plot E-Atomo Diagnostics Pvt. Ltd sector 2, 70127 Paramatta Road, Lacharoot 13001 NSW, Australia Plot E-Atomo Diagnostics Pvt. Ltd sector 1 & 2, 70127 Paramatta Road, Lacharoot 13001 NSW, Australia Technology Park, Mountbatten 79405, South Africa	1 T/kit; 1 T/kit; 1 T/kit; 1 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	HIV/SyR RDT	# First Response HIV+2 Syphilis Combo Card Test	120F RC-25; 120F RC-30; 120F RC-35; 120F RC-40; 120F RC-100	RoW	Premier Medical Corporation Pvt Ltd Limited	Salemang, Gujarat, India	30 T/kit; 50 T/kit; 50 T/kit; 300 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	IFPW01535 TC-06; IFPW02125 TC-25; IFPW02135 TC-40; IFPW02135 TC-60A	RoW	IN THE PRODUCTS, INC	308, Wengang Rd, Anyang IND. AREA, Huangpi, Xiamen, 350021, China	25 T/kit; 40 T/kit; 40 T/kit; 40 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	HCV RDT	Rapid Anti-HCV Test	IFPW01135 TC-40; IFPW01135 TC-25; IFPW01135 TC-10	RoW	IN THE PRODUCTS, INC	308, Wengang Rd, Anyang IND. AREA, Huangpi, Xiamen, 350021, China	40 T/kit; 25 T/kit; 40 T/kit; 40 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	Malaria RDT	Adva/Malaria Pf Rapid Malaria Ag Detection Test	OD-DMA-RK-AVA/AD-20/004-025	RoW	Advity Chemical Pvt Ltd,	PLOT No A-334/3,36/3,38 & A-337/3,339 flood no. 215, 26, Wagle Industrial Estate Thane 400 604 India	25 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	Malaria RDT	# Malaria Eliminate Malaria Pf and Nucleic Malaria Pf	OSF K14-01; OSF K14-02; OSF K14-03; OSF K14-04	CE mark	Abbott Diagnostics Korea Inc	Plot 2-46, Hageuro 13 Bongeom, Hageuro-gu, Yeosu-si, Gyeonggi-do 17099, Republic of Korea Plot 2-65, Bongeom-gu, Hageuro-gu, Yeosu-si, Gyeonggi-do 17099, Republic of Korea	25 T/kit; 25 T/kit; 17 kit x 25 each; 17 kit x 25 each	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2019	HV NAT	# m-RMA HIV-1/2 VL	27015-V50	RoW	Abbott Rapid Diagnostics GmbH	Ohringweg 1, D-07743 Jena, Germany	50 cartridges/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2018	Malaria RDT	First Response Malaria Antigen P (sd)urum (HBP-2) Card test	P13BRC-25a; P13BRC-10; P13BRC-25; P13BRC-30	RoW	Premier Medical Corporation Limited	Plot 1-A1-302, GDC, Sangam 396 155, Valsad, Gujarat, India Plot 2-32-15A, Shree Ganesh Industrial Estate, Kachigani, Main Chauri, Gandhinagar 390213, India	25 x single kit; 10 x single kit; 25 x single kit; 30 x single kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2018	Malaria RDT	First Response Malaria Ag. P1 / P x Card Test	P13BRC-10; P13BRC-25; P13BRC-10; P13BRC-25	RoW	Premier Medical Corporation Limited	Plot 1-A1-302, GDC, Sangam 396 155, Valsad, Gujarat, India Plot 2-32-15A, Shree Ganesh Industrial Estate, Kachigani, Main Chauri, Gandhinagar 390213, India	25 x single test; 30 x multi test; 25 x multi test	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2018	Malaria RDT	Bilcline Malaria Ag P1/Px Ag	OSF K12-20; OSF K12-3	CE mark	Abbott Diagnostics Korea Inc	65 Bongeom-gu, Gyeonggi-do, Yeosu-si, Gangneung, South Korea	25 T/kit; 1 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2018	HV RDT for self-testing	INSTE HIV Self Test	90.1071	RoW	bioMérieux Laboratories Inc.	Richmond, British Columbia, Canada	1 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2018	HIV RDT	One Step HIV-2/21 Antibody Rapid Assay/Plasma Test	W006-C492; W006-P045; W006-P046; W006-P047; W006-P048; W006-C493-F; W006-P049; W006-P050; W006-P051	RoW	Guangzhou Wonle Biotech Co., Ltd	Et Lichuan Road, Shaoxing City, Jiangsu District, Guanyang, 315060, Republic of China	25 T/kit; 25 T/kit; 25 T/kit; 25 T/kit; 40 T/kit; 40 T/kit; 40 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00
2018	Malaria RDT	One Step test for Malaria Pf/Px Ag MERS/SCHEIN Malaria Pf/Px Ag	M1BPD-02; M1BPD-03; M1BPD-04; M1BPD-05	CE marked	Merf Diagnostics Pvt. Ltd	D1-03, Merf Park, Survey No. 1352/18 & 174/22, Madanand Nagar, Chhota, Vapi 396519, Gujarat, India	30 T/kit; 25 T/kit; 50 T/kit; 30 T/kit	https://statement.whoi.int.gov/whoi/public_report/submit/whoi/2019-0324-01-01-00