



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 November 2023

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2019	HIV RDT for self-testing	SURE CHECK HIV Self-Test	60-9508-0	RoW	Chembio Diagnostic Systems, Inc	3661 Horseblock Road, Medford, NY 11763 USA	1 T/kit
2019	HPV Virological Technologies	Abbott RealTime High Risk HPV	Q2N09-092; and Q2N09-080	CE-marked	Abbott GmbH	Max-Planck-Ring 2, Wiesbaden, 65205, Germany	96 T/kit
2019	HIV RDT	First Response HIV 1-2.0 Card test (Version 2.0)	PI05FRC05; PI05FRC10; PI05FRC25; PI05FRC30; PI05FRC50; PI05FRC60; PI05FRC100	RoW	Premier Medical Corporation Private Limited	A1-302, GIDC, Sarigam, India	5 T/kit 10 T/kit 25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit
2019	HBAg RDT	Determine HBsAg 2	7D2942; 7D2943; 7D2943 SET	RoW	Abbott Diagnostics Medical Co. Ltd	357 Matsuhisa, Matsudo-shi, 270-2214, Chiba-Ken, Japan	20 T/kit 100 T/kit 100 T/kit
2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02; and 8C89-01	CE-marked	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Green-shi, Niigata, Japan	100 T/kit
2019	HIV RDT for self-testing	# Mylan HIV Self Test	AKS1001-03; AKS1001-03-01; AKS1001-03-02; AKS1001-03-03	RoW	Atomo Diagnostics Pvt. Ltd	Site 1: Atomo Diagnostics Pvt. Ltd at Level 2, 701-703 Parramatta Road, Leichardt 2040 NSW, Australia Site 2: Lateral Flow Laboratories (LFL) at Unit 1 & 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Nulandberg 7563, South Africa	1 T/kit 1 T/kit 1 T/kit 1 T/kit
2019	HIV/Syp RDT	First Response HIV1-2/Syphilis Combo Card Test	ID0ERC05; ID0ERC06; ID0ERC50; ID0ERC60; ID0ERC100	RoW	Premier Medical Corporation Private Limited	Sarigam, Gujarat, India	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit
2019	HIV RDT	#ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40 ITPW02152-TC25 ITPW02153-TC40 ITPW02153-TC05A ITPW02154-TC40	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit 40 T/kit 40 T/kit
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