

**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: 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
2023	HIV NAT	SAMBA II HIV-1 Qual Whole Blood Test	4500-12	CE-mark	Diagnostics for the Real World Ltd	Diagnostics for the Real World in San Jose, CA, USA	12 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-samba-whole-blood-test-pqdx-0458-072-00">https://extranet.who.int/pgweb/WHOPR/public-report-samba-whole-blood-test-pqdx-0458-072-00</a>
2023	HPV Virological Technologies	cobas HPV	07460155190, 07460171190, 07002238190, 06997546190, 06997511190, 06997538190, 06997503190	CE-mark	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	480 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hpv-pqdx-0468-046-00">https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hpv-pqdx-0468-046-00</a>
2022	Syphilis RDT	Determine Syphilis TP	7D2452, 7D2453 and 7D2453SET	RoW	Abbott Diagnostics Medical Co., Ltd.	Abbott Diagnostics Medical Co., Ltd, located at 357 Matsuhidai, Chiba-ken Matsudo-shi, 270-2214, Japan	30 T/kit 100 T/kit 100 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-determine-syphilis-tp-pqdx-0485-013-00">https://extranet.who.int/pgweb/WHOPR/public-report-determine-syphilis-tp-pqdx-0485-013-00</a>
2022	HCV NAT	Xpert HCV VL Fingerstick	GXHCV-FS-CE-10	CE-mark	Cepheid AB	Röntgenvägen 5, SE-171 54 Solna, Sweden	10 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-xpert-hcv-vl-fingerstick-pqdx-0453-070-00">https://extranet.who.int/pgweb/WHOPR/public-report-xpert-hcv-vl-fingerstick-pqdx-0453-070-00</a>
2022	HIV RDT	Panbio HIV Verification Test	29011-W20 29011AW20	RoW	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1, Jena, Germany	20 T/kit 20 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-panbio-hiv-verification-test-pqdx-0480-032-00">https://extranet.who.int/pgweb/WHOPR/public-report-panbio-hiv-verification-test-pqdx-0480-032-00</a>
2022	Malaria RDT	One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	RPWMPH-02, RPWMPH-03, RPWMPH-04	RoW	Meril Diagnostics Pvt. Ltd	Second Floor, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India	10 T/kit 25 T/kit 50 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-pqdx-0470-074-00">https://extranet.who.int/pgweb/WHOPR/public-report-one-step-test-malaria-pf-hrp-ii-ag-meriscreen-pqdx-0470-074-00</a>
2022	HIV NAT	cobas HIV-1 Nucleic acid test for use on the cobas 4800 System	08792992190, 06979572190, 06979513190, 06979521190, 05235863190, 05235871190, 06979556190, 06979530190	CE-mark	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit; 10 Sets; 240 T/kit; 960 T/kit; 240 T/kit; 960 T/kit; 240 T/kit; 240 T/kit; 1 T/kit;	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hiv-1-nucleic-acid-test-use-cobas-4800-system-pqdx-0710-118-00">https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hiv-1-nucleic-acid-test-use-cobas-4800-system-pqdx-0710-118-00</a>
2022	HIV RDT for self-testing	Wondfo HIV Self-Test	W006P0058, W006P0059, and W006P0060	RoW	Guangzhou Wondfo Biotech Co., Ltd	8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China	20 T/kit 100T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-wondfo-hiv-self-test-pqdx-0357-004-01">https://extranet.who.int/pgweb/WHOPR/public-report-wondfo-hiv-self-test-pqdx-0357-004-01</a>
2022	HIV RDT for self-testing	CheckNOW HIV SELF TEST	29012-W01	RoW	Abbott Rapid Diagnostics Jena GmbH	Loebstedter Str. 103-105, Jena, Germany	1 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-checknow-hiv-self-test-pqdx-0481-032-00">https://extranet.who.int/pgweb/WHOPR/public-report-checknow-hiv-self-test-pqdx-0481-032-00</a>
2022	HIV RDT	TrinScreen HIV	5551100	RoW	Trinity Biotech Manufacturing Ltd	1 Southern Cross IDA Business Park in Bray, Ireland	100 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-trinscreen-hiv-pqdx-0473-052-00">https://extranet.who.int/pgweb/WHOPR/public-report-trinscreen-hiv-pqdx-0473-052-00</a>
2021	HIV NAT	# cobas HIV-1 Quantitative nucleic acid test for use on the cobas 4800 System	06979599190, 06979572190, 06979513190, 06979521190, 05235863190, 05235871190, 06979556190, 06979530190, 06979548190	CE-mark	Roche Diagnostics GmbH	Sandhofer Strasse 116, Mannheim, 68305 Germany	120 T/kit; 10 Sets; 240 T/kit; 960 T/kit; 240 T/kit; 960 T/kit; 240 T/kit; 240 T/kit; 960 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-4800-system-pqdx-0373-118">https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-4800-system-pqdx-0373-118</a>
2021	HCV NAT	# cobas HCV (Quantitative nucleic acid test for use on cobas 5800/6800/8800 Systems)	6997732190 09040765190	CE-mark	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hcv-quantitative-nucleic-acid-test-use-cobas-68008800-systems-pqdx-0465">https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hcv-quantitative-nucleic-acid-test-use-cobas-68008800-systems-pqdx-0465</a>
2021	Syphilis RDT	First Response Syphilis Anti-TP Card Test	PI08FRC25, PI08FRC50, PI08FRC100, PI08FRC25-SA	RoW	Premier Medical Corporation Private 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 T/kit 50 T/kit 100 T/kit 25 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-first-response-syphilis-anti-tp-card-test-pqdx-0471-010-00">https://extranet.who.int/pgweb/WHOPR/public-report-first-response-syphilis-anti-tp-card-test-pqdx-0471-010-00</a>
2020	HIV NAT	# cobas HIV-1 Quantitative nucleic acid test for use on the cobas 5800/6800/8800 Systems	07000995190 09040803190	CE-mark	Roche Molecular Systems, Inc.	Sandhofer Strasse 116, Mannheim, 68305 Germany	96 T/kit 192 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-68008800-systems-pqdx-0365">https://extranet.who.int/pgweb/WHOPR/public-report-cobas-hiv-1-quantitative-nucleic-acid-test-use-cobas-68008800-systems-pqdx-0365</a>
2020	HIV RDT	# MERISCREEN HIV 1-2 WB	HVWRPD-01 HVWRPD-02 HVWRPD-06 HVWRPD-07 HVWRPD-08	CE-mark	Meril Diagnostics Pvt. Ltd.	Second Floor, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India	30 T/kit 40 T/kit 50 T/kit 10 T/kit 100 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-meriscreen-hiv-1-2-wb-pqdx-0464-074-00">https://extranet.who.int/pgweb/WHOPR/public-report-meriscreen-hiv-1-2-wb-pqdx-0464-074-00</a>
2020	Malaria RDT	Paracheck PF - Rapid Test for P. Falciparum Malaria Device (Ver. 3)	302030025, 302030005, 302030010, 302030025, 302030100, 302030025(1T)	CE-mark	Orchid Biomedical Systems – A Division of Tulip Diagnostics (P) Ltd	Plot nos 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403722, India	1T/kit, 5 T/kit 10 T/kit 25 T/kit 100 T/kit 25 x 1 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-paracheck-pf-rapid-test-falciparum-malaria-device-ver-3-pqdx-0321-024-00">https://extranet.who.int/pgweb/WHOPR/public-report-paracheck-pf-rapid-test-falciparum-malaria-device-ver-3-pqdx-0321-024-00</a>

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Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Link to access public report
2020	Malaria RDT	One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02, MHLRPD-03, MHLRPD-04, MHLRPD-05.	CE-mark	Meril Diagnostics Pvt. Ltd	Second Floor, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India	30 T/kit 10 T/kit 25 T/kit 50 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-one-step-test-malaria-pfpan-ag-meriscreen-malaria-pfpan-ag-pqdx-0330-074-00">https://extranet.who.int/pgweb/WHOPR/public-report-one-step-test-malaria-pfpan-ag-meriscreen-malaria-pfpan-ag-pqdx-0330-074-00</a>
2020	CD4 Technologies	# VISITECT CD4 Advanced Disease	AB376	CE-mark	AccuBio Ltd	AccuBio Ltd located at Hillfoots Business, Village, Alva, FK12 5DQ United Kingdom.	25 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-visitect-cd4-advanced-disease-pqdx-0384-077-00">https://extranet.who.int/pgweb/WHOPR/public-report-visitect-cd4-advanced-disease-pqdx-0384-077-00</a>
2020	HIV RDT	STANDARD Q HIV 1/2 Ab 3-Line Test	09HIV30D; 09HIV30DM	RoW	SD Biosensor, Inc	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit; 25 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-standard-q-hiv-12-ab-3-line-test-pqdx-0383-117-00">https://extranet.who.int/pgweb/WHOPR/public-report-standard-q-hiv-12-ab-3-line-test-pqdx-0383-117-00</a>
2020	Malaria RDT	parascreeen - Rapid test for Malaria Pan/Pf	503030025(1T) 503030010; 503030025; 503030050; 503030100	CE-mark	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.	M46-47, Phase III B, Verna, Goa, 403722, India	25 x 1 T/kit 10 T/kit 25 T/kit 50 T/kit 100 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-parascreeen-rapid-test-malaria-panpf-pqdx-0291-025-00">https://extranet.who.int/pgweb/WHOPR/public-report-parascreeen-rapid-test-malaria-panpf-pqdx-0291-025-00</a>
2020	Malaria RDT	# Falcivax - Rapid test for Malaria Pv/Pf	503010025(1T) 503010010; 503010025; 503010050; 503010100	CE-mark	Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.	M46-47, Phase III B, Verna, Goa, 403722, India	25 x 1 T/kit 10 T/kit 25 T/kit 50 T/kit 100 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-falcivax-rapid-test-malaria-pvpf-pqdx-0290-025-00">https://extranet.who.int/pgweb/WHOPR/public-report-falcivax-rapid-test-malaria-pvpf-pqdx-0290-025-00</a>
2020	HIV/Syp RDT	STANDARD Q HIV/Syphilis Combo Test	09HIV20D	RoW	SD Biosensor, Inc	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit	<a href="https://extranet.who.int/pgweb/WHOPR/public-report-standard-q-hivsyphilis-combo-test-pqdx-0382-117-00">https://extranet.who.int/pgweb/WHOPR/public-report-standard-q-hivsyphilis-combo-test-pqdx-0382-117-00</a>
2020	HCV NAT	# Alinity m HCV	08N50-090; 08N50-080; 08N50-070	CE-mark	Abbott Molecular Inc	1300 East Touhy Avenue, Des Plaines, IL 60018 USA	4 trays of 48 T/kit 12 tubes of each control 4 tubes x 1.95 mL	<a href="https://extranet.who.int/pgweb/content/public-report-alitym-hcv-pqdx-0461-027-00">https://extranet.who.int/pgweb/content/public-report-alitym-hcv-pqdx-0461-027-00</a>
2020	Malaria RDT	STANDARD Q Malaria P.f/P.v Ag Test	09MAL20D	CE-mark	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-standard-q-malaria-pfv-ag-test-pqdx-0348-117-00">https://extranet.who.int/pgweb/content/public-report-standard-q-malaria-pfv-ag-test-pqdx-0348-117-00</a>
2020	Malaria RDT	STANDARD Q Malaria P.f Pan Ag Test	09MAL30D	CE-mark	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-standard-q-malaria-pfpan-ag-test-pqdx-0347-117-00">https://extranet.who.int/pgweb/content/public-report-standard-q-malaria-pfpan-ag-test-pqdx-0347-117-00</a>
2020	Malaria RDT	STANDARD Q Malaria P.f Ag Test	09MAL10D	CE-mark	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-standard-q-malaria-pf-ag-test-pqdx-0346-117-00">https://extranet.who.int/pgweb/content/public-report-standard-q-malaria-pf-ag-test-pqdx-0346-117-00</a>
2020	HCV RDT	STANDARD Q HCV Ab Test	09HCV10D	RoW	SD Biosensor, Inc.	74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea	25 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-standard-q-hcv-ab-test-pqdx-0360-117-00">https://extranet.who.int/pgweb/content/public-report-standard-q-hcv-ab-test-pqdx-0360-117-00</a>
2020	HCV EIA	Monolisa HCV Ag-Ab ULTRA V2	72561 and 72562	CE-mark	Bio-Rad	3, bd Raymond Poincaré, 92430, Marne La Coquette, France and Route de Cassel, 59114, Steenvoorde, France	96 T/kit 480 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-monolisa-hcv-ag-ab-ultra-v2-pqdx-0229-031-00">https://extranet.who.int/pgweb/content/public-report-monolisa-hcv-ag-ab-ultra-v2-pqdx-0229-031-00</a>
2019	HCV NAT	Abbott RealTime HCV	4186-90; 4186-80; and 4186-70	CE-mark	Abbott Molecular Inc	1300 East Touhy Avenue, Des Plaines, IL 60018 USA	96 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hcv-pqdx-0450-027-00">https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hcv-pqdx-0450-027-00</a>
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	<a href="https://extranet.who.int/pgweb/content/public-report-sure-check-hiv-self-test-pqdx-0054-006-01">https://extranet.who.int/pgweb/content/public-report-sure-check-hiv-self-test-pqdx-0054-006-01</a>
2019	HPV Virological Technologies	Abbott RealTime High Risk HPV	02N09-092; and 02N09-080	CE-mark	Abbott GmbH	Max-Planck-Ring 2, Wiesbaden, 65205, Germany	96 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-abbott-realtime-high-risk-hpv-pqdx-0455-180-00">https://extranet.who.int/pgweb/content/public-report-abbott-realtime-high-risk-hpv-pqdx-0455-180-00</a>
2019	HIV RDT	First Response HIV 1-2.O Card test (Version 2.0)	PI05FRC05; PI05FRC10; PI05FRC25; PI05FRC30; 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	<a href="https://extranet.who.int/pgweb/content/public-report-first-response-hiv-1-2-o-card-test-pqdx-0363-010-00">https://extranet.who.int/pgweb/content/public-report-first-response-hiv-1-2-o-card-test-pqdx-0363-010-00</a>
2019	HBSAg RDT	# Determine HBSAg 2	7D2942; 7D2943; 7D2943 SET	RoW	Abbott Diagnostics Medical Co.Ltd	357 Matsuhidai, Matsudo-shi, 270-2214, Chiba-ken, Japan	20 T/kit 100 T/kit 100 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-determine-hbsag-2-pqdx-0451-013-00">https://extranet.who.int/pgweb/content/public-report-determine-hbsag-2-pqdx-0451-013-00</a>

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2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02; and 8C89-01	CE-mark	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, Japan	100 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-architect-hcv-ag-assay-pqdx-0374-130-00">https://extranet.who.int/pgweb/content/public-report-architect-hcv-ag-assay-pqdx-0374-130-00</a>
2019	HIV RDT for self-testing	# Mylan HIV Self Test	ARST001-03; ARST001-03-01; ARST001-03-02; ARST001-03-03	RoW	Atomo Diagnostics Pty. Ltd	Site 1: Atomo Diagnostics Pty 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, Muizenberg, 7945, South Africa	1 T/kit; 1 T/kit; 1 T/kit; 1 T/kit.	<a href="https://extranet.who.int/pgweb/content/public-report-mylan-hiv-self-test-pqdx-0320-090-00">https://extranet.who.int/pgweb/content/public-report-mylan-hiv-self-test-pqdx-0320-090-00</a>
2019	HIV/Syp RDT	# First Response HIV1+2/Syphilis Combo Card Test	I20FRC25; I20FRC30; I20FRC50; I20FRC60; I20FRC100	RoW	Premier Medical Corporation Private Limited	Sarigam, Gujarat, India	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-first-response%2%AF-hiv12syphilis-combo-card-test-pqdx-0364-010-00">https://extranet.who.int/pgweb/content/public-report-first-response%2%AF-hiv12syphilis-combo-card-test-pqdx-0364-010-00</a>
2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40; ITPW02152-TC25; ITPW02153-TC40 ITPW02153-TC40SA	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	<a href="https://extranet.who.int/pgweb/content/public-report-one-step-anti-hiv-12-test-pqdx-0372-017-00">https://extranet.who.int/pgweb/content/public-report-one-step-anti-hiv-12-test-pqdx-0372-017-00</a>
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	<a href="https://extranet.who.int/pgweb/content/public-report-rapid-anti-hcv-test-pqdx-0371-017-00">https://extranet.who.int/pgweb/content/public-report-rapid-anti-hcv-test-pqdx-0371-017-00</a>
2019	Malaria RDT	AdvDx Malaria Pf Rapid Malaria Ag Detection Test	00-DKM-RK-MALADX-004-025	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	25 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-advdx-malaria-pf-rapid-malaria-ag-detection-test-pqdx-0345-101-00">https://extranet.who.int/pgweb/content/public-report-advdx-malaria-pf-rapid-malaria-ag-detection-test-pqdx-0345-101-00</a>
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	<a href="https://extranet.who.int/pgweb/content/public-report-pqdx-0349-012-00">https://extranet.who.int/pgweb/content/public-report-pqdx-0349-012-00</a>
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	<a href="https://extranet.who.int/pgweb/content/public-report-m-pima-hiv-12-vl-pqdx-0359-032-00">https://extranet.who.int/pgweb/content/public-report-m-pima-hiv-12-vl-pqdx-0359-032-00</a>
2018	Malaria RDT	First Response Malaria Antigen P. falciparum (HRP2) Card Test	PI13FRC25; 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	<a href="https://extranet.who.int/pgweb/content/public-report-first-response%2%AF-malaria-antigen-p-falciparum-hrp2-card-test-pqdx-0283-010-00">https://extranet.who.int/pgweb/content/public-report-first-response%2%AF-malaria-antigen-p-falciparum-hrp2-card-test-pqdx-0283-010-00</a>
2018	Malaria RDT	First Response Malaria Ag. P.f. / P.v. Card Test	PI19FRC10s; PI19FRC25; 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	<a href="https://extranet.who.int/pgweb/content/public-report-first-response%2%AFmalaria-ag-pf-pv-card-test-pqdx-0329-010-00">https://extranet.who.int/pgweb/content/public-report-first-response%2%AFmalaria-ag-pf-pv-card-test-pqdx-0329-010-00</a>
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	<a href="https://extranet.who.int/pgweb/content/public-report-pdx-0297-012-00">https://extranet.who.int/pgweb/content/public-report-pdx-0297-012-00</a>
2018	HIV RDT for self-testing	INSTI HIV Self Test	90-1071	RoW	bioLytical Laboratories Inc.	Richmond, British Columbia, Canada	1T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-insti-hiv-self-test-pqdx-0002-002-01">https://extranet.who.int/pgweb/content/public-report-insti-hiv-self-test-pqdx-0002-002-01</a>
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; 40T/kit; 40T/kit; 40T/kit; 40T/kit;	<a href="https://extranet.who.int/pgweb/content/public-report-one-step-hiv12-whole-bloodserumplasma-test-pqdx-0357-004-00">https://extranet.who.int/pgweb/content/public-report-one-step-hiv12-whole-bloodserumplasma-test-pqdx-0357-004-00</a>
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.	<a href="https://extranet.who.int/pgweb/content/public-report-one-step-test-malaria-pf-pv-ag-meriscreen-malaria-pf-pv-ag-pqdx-0294-074-00">https://extranet.who.int/pgweb/content/public-report-one-step-test-malaria-pf-pv-ag-meriscreen-malaria-pf-pv-ag-pqdx-0294-074-00</a>

**WHO list of prequalified in vitro diagnostic products**

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 Last 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
2018	Malaria RDT	First Response Malaria Ag, pLDH/HRP2 Combo Card Test	P116FRC10s P116FRC25s P116FRC25 P116FRC30	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 × single kit 25 × single kit 25 × multi kit 30 × multi kit	<a href="https://extranet.who.int/pqweb/content/public-report-first-response%2FAE-malaria-ag-pldhrp2-combo-card-test-pqdx-0285-010-00">https://extranet.who.int/pqweb/content/public-report-first-response%2FAE-malaria-ag-pldhrp2-combo-card-test-pqdx-0285-010-00</a>
2018	CD4 Technologies	CyFlow Counter System with CD4 easy count kit and CD4% easy count kit	CY-S-3023; 05-8401; and 05-8405	CE-marked	Sysmex Partec GmbH	site 1: Arndtstr. 11a-b, 02826 Görlitz, Germany; and site 2: Exbio Praha a.s., Nad Safinou II 341, 252 50 Vestec, Czech Republic	100 T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-cyflow-counter-system-cd4-easy-count-kit-and-cd4-easy-count-kit-pqdx-0350-081">https://extranet.who.int/pqweb/content/public-report-cyflow-counter-system-cd4-easy-count-kit-and-cd4-easy-count-kit-pqdx-0350-081</a>
2018	HPV Virological Technologies	care HPV Test	614015	CE-mark	QIAGEN GmbH	site 1: QIAGEN Sciences, Germantown, 20874, United States site 2: QIAGEN Shenzhen Co., Shenzhen China	96 T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-carehpv-test-pqdx-0085-028-00">https://extranet.who.int/pqweb/content/public-report-carehpv-test-pqdx-0085-028-00</a>
2018	HCV EIA	INNOTEST HCV Ab IV	80068; 80330	CE-mark	Fujirebio Europe NV	Ghent, Belgium	192T/kit 480T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-innotest-hcv-ab-iv-pqdx-0201-073-00">https://extranet.who.int/pqweb/content/public-report-innotest-hcv-ab-iv-pqdx-0201-073-00</a>
2017	HBsAg RDT	Bioline HBsAg WB	01FK10W	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-sd-bioline-hbsag-wb-pqdx-0219-012-00">https://extranet.who.int/pqweb/content/public-report-sd-bioline-hbsag-wb-pqdx-0219-012-00</a>
2017	HIV RDT	Genie Fast HIV 1/2	72327; 72347; 72330	CE-mark	Bio-Rad	Marne La Coquette, France	25T/kit 50T/kit 50T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-genie%2F84%A2-fast-hiv-12-pqdx-0153-031-00">https://extranet.who.int/pqweb/content/public-report-genie%2F84%A2-fast-hiv-12-pqdx-0153-031-00</a>
2017	HPV Virological Technologies	Xpert HPV	GXHPV-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-xpert-hpv-pqdx-0268-070-00">https://extranet.who.int/pqweb/content/public-report-xpert-hpv-pqdx-0268-070-00</a>
2017	Virological Technologies	Aptima HIV-1 Quant Dx Assay	PRD-03000 (PRD-03002, PRD-03001); 303014; PRD-03003; and 303095	CE-mark	Hologic, Inc.	San Diego, USA	100T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-aptima%2F84%A2-hiv-1-quant-dx-assay-pqdx-0236-078-00">https://extranet.who.int/pqweb/content/public-report-aptima%2F84%A2-hiv-1-quant-dx-assay-pqdx-0236-078-00</a>
2017	HIV RDT for self-testing	OraQuick HIV Self-Test	5X4-1000; 5X4-1001; 5X4-2001; Country specific variations are documented through a suffix "###" to the product code on	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand	50T/kit; 250T/kit; 110T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-oraquick-hiv-self-test-pqdx-0159-055-01">https://extranet.who.int/pqweb/content/public-report-oraquick-hiv-self-test-pqdx-0159-055-01</a>
2017	Virological Technologies	# Xpert HIV-1 Viral Load	GXHIV-VL-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-xpert%2FAE-hiv-1-viral-load-genexpert%2FAE-dx-genexpert%2FAE-infinity-48-genexpert%2FAE">https://extranet.who.int/pqweb/content/public-report-xpert%2FAE-hiv-1-viral-load-genexpert%2FAE-dx-genexpert%2FAE-infinity-48-genexpert%2FAE</a>
2017	HCV NAT	Xpert HCV Viral Load	GXHCV-VL-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-xpert%2FAE-hcv-viral-load-pqdx-0260-070-00">https://extranet.who.int/pqweb/content/public-report-xpert%2FAE-hcv-viral-load-pqdx-0260-070-00</a>
2017	HIV Confirmatory Assay	Genieus HIV 1/2 Confirmatory Assay with Genieus HIV1/2 Confirmatory Controls	72460; and 72329	CE-mark	Bio-Rad	Marnes-La-Coquette, France	20T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-geenius-hiv-12-confirmatory-assay-geenius-hiv12-confirmatory-controls-pqdx">https://extranet.who.int/pqweb/content/public-report-geenius-hiv-12-confirmatory-assay-geenius-hiv12-confirmatory-controls-pqdx</a>
2017	HCV RDT	OraQuick HCV Rapid Antibody Test Kit	1001-0270; 001-0274	CE-mark	OraSure Technologies, Inc.	Bethlehem, USA	25T/kit; 100T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-oraquick-hcv-rapid-antibody-test-kit-pqdx-0244-055-00">https://extranet.who.int/pqweb/content/public-report-oraquick-hcv-rapid-antibody-test-kit-pqdx-0244-055-00</a>
2016	HIV RDT	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	R-401-50-C-2; KH-R-02; and A-GOLD-01	RoW	Shanghai Kehua Bio-engineering Co., Ltd	Shanghai, PR China	50T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-diagnostic-kit-hiv-12-antibody-colloidal-gold-v2-pqdx-0267-037-00">https://extranet.who.int/pqweb/content/public-report-diagnostic-kit-hiv-12-antibody-colloidal-gold-v2-pqdx-0267-037-00</a>
2016	HCV RDT	Bioline HCV	02FK10; 02FK16; 02FK17	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit 25T/kit 30T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-sd-bioline-hcv-pqdx-0257-012-00">https://extranet.who.int/pqweb/content/public-report-sd-bioline-hcv-pqdx-0257-012-00</a>
2016	HIV RDT	# Determine HIV Early Detect	7D2842; 7D2843; 7D2843SET	RoW	Alere Medical Co. Ltd.	Matsudo-shi, Chiba-ken, Japan	20T/kit; 100T/kit; 100T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-alere%2F84%A2-hiv-combo-pqdx-0243-013-00">https://extranet.who.int/pqweb/content/public-report-alere%2F84%A2-hiv-combo-pqdx-0243-013-00</a>
2016	HIV NAT	Xpert HIV-1 Qual Assay	GXHIV-QA-CE-10	CE-mark	Cepheid AB	Solna, Sweden	10 cartridges/kit and instrument	<a href="https://extranet.who.int/pqweb/content/public-report-xpert%2FAE-hiv-1-qual-assay-pqdx-0259-070-00">https://extranet.who.int/pqweb/content/public-report-xpert%2FAE-hiv-1-qual-assay-pqdx-0259-070-00</a>
2016	HIV NAT	m-PIMA HIV-1/2 Detect	270110050; 270110010; 27011-W50 270300001	CE-mark RoW	Alere Technologies GmbH	Jena, Germany	50 cartridges/kit 10 cartridges/kit 50 cartridges/kit Instrument	<a href="https://extranet.who.int/pqweb/content/public-report-m-pima-hiv-12-detect-pqdx-0226-032-00">https://extranet.who.int/pqweb/content/public-report-m-pima-hiv-12-detect-pqdx-0226-032-00</a>
2016	HIV RDT	DPP HIV 1/2 Assay	65-9506-0	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	20T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-dpp%2FAE-hiv-12-assay-pqdx-0053-006-00">https://extranet.who.int/pqweb/content/public-report-dpp%2FAE-hiv-12-assay-pqdx-0053-006-00</a>

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Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Link to access public report
2016	HIV RDT	OraQuick HIV 1/2 Rapid Antibody Test	5x4-0010; 5x4-0014; 5x4-0062; 5x-0012; 5x-0015	RoW	OraSure Technologies, Inc.	site 1: Bethlehem, USA site 2: Petchabun, Thailand site 3: Ayutthaya, Thailand	100T/kit; 100T/kit; 100T/kit 500T/kit 500T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-oraquick-hiv-12-rapid-antibody-test-pqdx-0159-055-00">https://extranet.who.int/pgweb/content/public-report-oraquick-hiv-12-rapid-antibody-test-pqdx-0159-055-00</a>
2016	HBsAg EIA	DS-EIA-HBsAg-0,01	B-1254/1,2; B-1252/1,2; B-1255/1,2; B-1256/1,2; B-231/1,2	CE-mark	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/kit; 192T/kit; 480T/kit; 96T/kit (for detection) or 48T/kit(for confirmation) 200T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-ds-eia-hbsag-e2%80%90e1a%e2%80%90hbsag%e2%80%90001-pqdx-0120-038-00">https://extranet.who.int/pgweb/content/public-report-ds-eia-hbsag-e2%80%90e1a%e2%80%90hbsag%e2%80%90001-pqdx-0120-038-00</a>
2016	HIV Confirmatory Assay	MP Diagnostics HIV Blot 2.2	11030-018; 11030-036	CE-mark	MP Biomedicals Asia Pacific Pte.Ltd.	Singapore, Singapore	18T/kit; 36T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-mp-diagnostics-hiv-blot-22-pqdx-0198-071-00">https://extranet.who.int/pgweb/content/public-report-mp-diagnostics-hiv-blot-22-pqdx-0198-071-00</a>
2016	HIV EIA	Aid anti-HIV 1+2 ELISA	WI-4396; WI-43480	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	96T/kit; 480T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-aid-anti-hiv-12-elisa-pqdx-0006-005-00">https://extranet.who.int/pgweb/content/public-report-aid-anti-hiv-12-elisa-pqdx-0006-005-00</a>
2016	HIV RDT	Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	WJ-1810; WJ-1810E; WJ-1850; WJ-1850E; WJ-1810EL; WJ-1850EL; WJ-18510EL	RoW	Beijing Wantai Biological Pharmacy Enterprise Co.	Beijing, China	10T/kit; 10T/kit; 50T/kit; 50T/kit; 10 T/kit; 50 T/kit; 10 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-rapid-test-antibody-human-immunodeficiency-virus-hiv-colloidal-gold-device">https://extranet.who.int/pgweb/content/public-report-rapid-test-antibody-human-immunodeficiency-virus-hiv-colloidal-gold-device</a>
2015	CD4 Technologies	Aquios CL flow cytometer	B30166; B39101; B39102; B25697; B25698; B23536; B23538; B23533; B23534; B23535; B25700; and B23502	CE-mark	Beckman Coulter Life Sciences	site 1: Miami, FL, USA (instrument site) site 2: Hialeah, FL, USA (reagent site)	50T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-aquios-cl-flow-cytometer-pqdx-0156-053-00">https://extranet.who.int/pgweb/content/public-report-aquios-cl-flow-cytometer-pqdx-0156-053-00</a>
2015	HIV/Syp RDT	Bioline HIV/Syphilis Duo	06FK30; 06FK35; 06FK37	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 25T/kit; 25T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-alere%e2%84%A2-hivsyphilis-duo-pqdx-0179-012-00">https://extranet.who.int/pgweb/content/public-report-alere%e2%84%A2-hivsyphilis-duo-pqdx-0179-012-00</a>
2015	Malaria RDT	Bioline Malaria Ag P.f/P.v	05FK80; 05FK81; 05FK82; 05FK83; 05FK86; 05FK87	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 25T/kit 17/kit x25 each 17/kit x25 each 10T/kit 25T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-pqdx-0125-012-00">https://extranet.who.int/pgweb/content/public-report-pqdx-0125-012-00</a>
2015	Malaria RDT	Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90; 05FK93; 05FK91; 05FK092	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 17/kit x25 each 25T/kit 17/kit x 25 each	<a href="https://extranet.who.int/pgweb/content/public-report-pqdx-0209-012-00">https://extranet.who.int/pgweb/content/public-report-pqdx-0209-012-00</a>
2015	HCV EIA	INNO-LIA HCV Score	80538	CE-mark	Fujirebio Europe NV	Zwijnaarde, Belgium	20T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-inno-lia-hcv-score-pqdx-0202-073-00">https://extranet.who.int/pgweb/content/public-report-inno-lia-hcv-score-pqdx-0202-073-00</a>
2015	HIV EIA	DS-EIA-HIV-AGAB-SCREEN	I-1654/1,2; I-1652/1,2; I-1656/1,2	CE-mark	RPC Diagnostics Systems	Nizhny Novgorod, Russia	96T/1 plate; 192T/2 plates; 480 T/5 plates	<a href="https://extranet.who.int/pgweb/content/public-report-ds-eia-hiv-agab-screen-pqdx-0106-038-00">https://extranet.who.int/pgweb/content/public-report-ds-eia-hiv-agab-screen-pqdx-0106-038-00</a>
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf/PAN) COMBO	<b>multi kit</b> (product codes: RMRM-02571; RMRM-02571CB; RMRM-02571RB; RMRM-02571RI; RMRM-05071; RMRM-05071CB; RMRM-05071RB and RMRM-05071RI) <b>single kit</b> (product codes: RMRU-02571; RMRU-02571CB; RMRU-02571RB; RMRU-02571RI; RMRU-04071; RMRU-04071CB; RMRU-04071RB and RMRU-04071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit.  25T/kit; 40T/kit.	<a href="https://extranet.who.int/pgweb/content/public-report-carestart%e2%84%A2-malaria-hrp2pldh-pfpan-combo-pqdx-0136-049-00">https://extranet.who.int/pgweb/content/public-report-carestart%e2%84%A2-malaria-hrp2pldh-pfpan-combo-pqdx-0136-049-00</a>
2015	Malaria RDT	**CareStart Malaria HRP2 (Pf)	<b>multi kit</b> (product codes: RMOM-02571; RMOM-02571CB; RMOM-02571RB; RMOM-02571RI; RMOM-05071; RMOM-05071CB; RMOM-05071RB and RMOM-05071RI) <b>single kit</b> (product codes: RMOU-02571; RMOU-02571CB; RMOU-02571RB; RMOU-02571RI; RMOU-05071; RMOU-05071CB; RMOU-05071RB and RMOU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit;  25T/kit; 40T/kit;	<a href="https://extranet.who.int/pgweb/content/public-report-carestart%e2%84%A2-malaria-hrp2-pf-pqdx-0137-049-00">https://extranet.who.int/pgweb/content/public-report-carestart%e2%84%A2-malaria-hrp2-pf-pqdx-0137-049-00</a>

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Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging	Link to access public report
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf/Pv) COMBO	<b>multi kit</b> (product codes: RMVM-02571; RMVM-02571CB; RMVM-02571RB; RMVM-02571RI; RMVM-05071; RMVM-05071CB; RMVM-05071RB and RMVM-05071RI) <b>single kit</b> (product codes: RMVU-02571; RMVU-02571CB; RMVU-02571RB; RMVU-02571RI; RMVU-05071; RMVU-05071CB; RMVU-05071RB and RMVU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pfv-combo-pqdx-0138-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pfv-combo-pqdx-0138-049-00</a>
2015	Malaria RDT	**CareStart Malaria HRP2/pLDH (Pf)	<b>multi kit</b> (product codes: RMPM-02571; RMPM-02571CB; RMPM-02571RB; RMPM-02571RI; RMPM-05071; RMPM-05071CB; RMPM-05071RB and RMPM-05071RI) <b>single kit</b> (product codes: RMPU-02571; RMPU-02571CB; RMPU-02571RB; RMPU-02571RI; RMPU-05071; RMPU-05071CB; RMPU-05071RB and RMPU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pf-pqdx-0188-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-hrp2pldh-pf-pqdx-0188-049-00</a>
2015	Malaria RDT	**CareStart Malaria pLDH (PAN)	<b>multi kit</b> (product codes: RMNM-02571; RMNM-02571CB; RMNM-02571RB; RMNM-02571RI; RMNM-05071; RMNM-05071CB; RMNM-05071RB and RMNM-05071RI) <b>single kit</b> (product codes: RMNU-02571; RMNU-02571CB; RMNU-02571RB; RMNU-02571RI; RMNU-05071; RMNU-05071CB; RMNU-05071RB and RMNU-05071RI)	RoW	Access Bio, Inc.	Somerset NJ, USA	25T/kit; 50T/kit 25T/kit; 40T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-pldh-pan-pqdx-0234-049-00">https://extranet.who.int/pqweb/content/public-report-carestart%E2%84%A2-malaria-pldh-pan-pqdx-0234-049-00</a>
2015	HIV Confirmatory Assay	INNO-Lia HIV I/II Score	80540	CE-mark	Fujirebio Europe NV	Ghent, Belgium	20T/kit	<a href="https://extranet.who.int/pqweb/WHOPR/public-report-inno-lia-hiv-iii-score-pqdx-0203-073-00">https://extranet.who.int/pqweb/WHOPR/public-report-inno-lia-hiv-iii-score-pqdx-0203-073-00</a>
2015	HIV EIA	Murex HIV Ag/Ab Combination	7G79-09 (GE41, 96 wells); and 7G79-11 (GE42, 480 wells)	CE-mark	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-murex-hiv-agab-combination-pqdx-0144-043-00">https://extranet.who.int/pqweb/content/public-report-murex-hiv-agab-combination-pqdx-0144-043-00</a>
2014	Virological Technologies	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	06693083190; 03051315001; 03279332001; 03587797190; 06989861190; 05807875001; 03516440001; and 28127387001	CE-mark	Roche Molecular Systems, Inc.	Branchburg, New Jersey, USA	48T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-cobas%C2%AE-ampli-prep-cobas%C2%AE-taqman%C2%AE-hiv-1-test-version-20-taqman-48-pqdx-0126-046">https://extranet.who.int/pqweb/content/public-report-cobas%C2%AE-ampli-prep-cobas%C2%AE-taqman%C2%AE-hiv-1-test-version-20-taqman-48-pqdx-0126-046</a>
2014	Virological Technologies	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	06693083190; 03587797190; 06989861190; 03051315001; 03121453001; 28127387001; 05807875001; and 03516440001	CE-mark	Roche Diagnostics GmbH	Mannheim, Germany	48T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-cobas%C2%AE-ampli-prep-cobas%C2%AE-taqman%C2%AE-hiv-1-test-version-20-taqman-96-pqdx-0147-046">https://extranet.who.int/pqweb/content/public-report-cobas%C2%AE-ampli-prep-cobas%C2%AE-taqman%C2%AE-hiv-1-test-version-20-taqman-96-pqdx-0147-046</a>
2014	HIV RDT	SURE CHECK HIV 1/2 Assay	HIV201 (60-9527-0),	RoW	Chembio Diagnostic Systems Inc.	Medford, NY, USA	25T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-sure-check-hiv-1-2-assay-pqdx-0054-006-00">https://extranet.who.int/pqweb/content/public-report-sure-check-hiv-1-2-assay-pqdx-0054-006-00</a>
2014	HBSAg EIA	Murex HBSAg Version 3 with Murex HBSAg Confirmatory Version 3	9F80-01; 9F80-05; 2G27-01	CE-mark	DiaSorin S.p.A UK Branch	Dartford, UK	96T/kit; 480T/kit 50T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pqdx-0121-043-00">https://extranet.who.int/pqweb/content/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pqdx-0121-043-00</a>
2014	Malaria RDT	ParaHIT f Ver. 1.0 Rapid Test for P. falciparum Malaria Device	55IC104-10; 55IC104-25; 55IC104-50	CE-mark	ARKRAY Healthcare Pvt. Ltd.	Sachin (Surat), India	10T/kit; 25T/kit; 50T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-parahit-f-ver-10-rapid-test-p-falciparum-malaria-device-pqdx-0062-023-00">https://extranet.who.int/pqweb/content/public-report-parahit-f-ver-10-rapid-test-p-falciparum-malaria-device-pqdx-0062-023-00</a>
2014	CD4 Technologies	# BD FACSPresto Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and BD FACSPresto Cartridges Kit	651000; 657681; 655495	CE-mark	Becton, Dickinson and Company, BD Biosciences	San Jose, California, USA	651000: instrument 657681: cartridge (100/box) 655495: pipette (100/box)	<a href="https://extranet.who.int/pqweb/content/public-report-bd-facspresto%E2%84%A2-near-patient-cd4-counter-bd-cd4cd4hb-cartridge-and-bd">https://extranet.who.int/pqweb/content/public-report-bd-facspresto%E2%84%A2-near-patient-cd4-counter-bd-cd4cd4hb-cartridge-and-bd</a>
2014	HIV RDT	# ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402WI, IHI-T402WA, IHI-T402WG, IHI-T402WB, IHI-T402WD, IHI-T402WE, IHI-T402WF	RoW	ABON Biopharm (Hangzhou) Co. Ltd.	Hangzhou, PR China	40T/kit; 40T/kit; 40T/kit; 40T/kit; 10T/kit; 40T/kit 10T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-abon%E2%84%A2-hiv-1-2-o-tri-line-human-immunodeficiency-virus-rapid-test-device-whole">https://extranet.who.int/pqweb/content/public-report-abon%E2%84%A2-hiv-1-2-o-tri-line-human-immunodeficiency-virus-rapid-test-device-whole</a>
2013	HIV RDT	INSTI HIV-1/HIV-2 Antibody Test	90-1013; 90-1010; 90-1022; 90-1021; 90-1038; 90-1064	RoW	BioLytical Laboratories, Inc.	Richmond, British Columbia, Canada	24T/kit without support material; 24T/kit with support materials; 48T/kit without support material; 48T/kit with support materials; 48T/kit with pipettes but no lancet, no alcohol	<a href="https://extranet.who.int/pqweb/content/public-report-insti-hiv-1-hiv-2-antibody-test-pqdx-0002-002-00">https://extranet.who.int/pqweb/content/public-report-insti-hiv-1-hiv-2-antibody-test-pqdx-0002-002-00</a>
2013	Malaria RDT	Bioline Malaria Ag P.f/Pan	05FK60; 05FK61; 05FK62; 05FK63; 05FK67	CE-mark	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	25T/kit; 25x1T/kit; 1T/kit; 25T/kit; 30T/kit	<a href="https://extranet.who.int/pqweb/content/public-report-sd-bioline-malaria-ag-pfpan-0030-012">https://extranet.who.int/pqweb/content/public-report-sd-bioline-malaria-ag-pfpan-0030-012</a>

**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: 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
2013	Virological Technologies	Abbott RealTime HIV-1 Qualitative (Manual)	4N66-90; 4N66-80; 6K12-24; 9K15-01; 4N66-01; and 4N66-66 (optional)	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack	<a href="https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-qualitative-manual-pqdx-0151-027-00">https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-qualitative-manual-pqdx-0151-027-00</a>
2013	Virological Technologies	Abbott RealTime HIV-1 Qualitative (m 2000sp)	4N66-90; 9K14-02; 9K15-01; 4N66-80; 4N66-01; 6K12-24; and 4N66-66 (optional)	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	96T/kit; 4x24T pack	<a href="https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-qualitative-m2000sp-pqdx-0084-027-00">https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-qualitative-m2000sp-pqdx-0084-027-00</a>
2013	HIV RDT	Bioline HIV-1/2 3.0	03FK10; 03FK16; 03FK17	RoW	Abbott Diagnostics Korea Inc	Giheung-gu, Republic of Korea	30T/kit; 25T/kit; 25T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-bioline-hiv-12-30-pqdx-0027-012-00">https://extranet.who.int/pgweb/content/public-report-bioline-hiv-12-30-pqdx-0027-012-00</a>
2013	HIV EIA	Genscreen ULTRA HIV Ag-Ab	72386; and 72388	CE-mark	Bio-Rad	Marnes La Coquette, France	96T/kit; 480T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-genscreen%E2%84%A2-ultra-hiv-ag-ab-pqdx-0096-031-00">https://extranet.who.int/pgweb/content/public-report-genscreen%E2%84%A2-ultra-hiv-ag-ab-pqdx-0096-031-00</a>
2012	HIV RDT	# Uni-Gold HIV	206502; 1206502N; 1206502E; 1206502N-100; 1206502-100; 1206502-C; 1206502E-C; 1206502-C100	RoW	Trinity Biotech Manufacturing Ltd.	Bray, Ireland	20T/kit; 20T/kit; 20T/kit; 100T/kit; 100T/kit; 20T/kit; 20T/kit; 100T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-uni-gold%E2%84%A2-hiv-pqdx-0149-052-00">https://extranet.who.int/pgweb/content/public-report-uni-gold%E2%84%A2-hiv-pqdx-0149-052-00</a>
2012	CD4 Technologies	Pima CD4 Test	260100025 and 260300003; 260100100; and 260300003	CE-mark	Abbott Rapid Diagnostics Jena GmbH	Orlweg 1, D-07743 Jena, Germany	25 cartridges/kit and instrument; 100 cartridges/kit and instrument	<a href="https://extranet.who.int/pgweb/content/public-report-pima%E2%84%A2-cd4-test-pqdx-0099-032-00">https://extranet.who.int/pgweb/content/public-report-pima%E2%84%A2-cd4-test-pqdx-0099-032-00</a>
2012	CD4 Technologies	# BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (Absolute CD4+, CD8+, and CD3+ Counts)	337858; 340166; 340167	CE-mark	Becton, Dickinson and Company, BD Biosciences	San Jose, CA, USA	337858: instrument system 340166: 25T /kit 340167: 50T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-bd-facscount%E2%84%A2-instrument-system-facscount%E2%84%A2-control-kit-and-bd-facscount%E2%84%A2">https://extranet.who.int/pgweb/content/public-report-bd-facscount%E2%84%A2-instrument-system-facscount%E2%84%A2-control-kit-and-bd-facscount%E2%84%A2</a>
2012	CD4 Technologies	# BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount CD4 Reagent Kit (Absolute and Percentage CD4+ Counts)	337858; 340166; 339010	CE-mark	Becton, Dickinson and Company, BD Biosciences	San Jose, CA, USA and Cayey, Puerto Rico	337858: instrument system 340166: 25T /kit 339010: 50T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-bd-facscounttm-instrument-system-facscounttm-control-kit-and-bd-facscounttm">https://extranet.who.int/pgweb/content/public-report-bd-facscounttm-instrument-system-facscounttm-control-kit-and-bd-facscounttm</a>
2012	Virological Technologies	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 48)	05212294190; 03587797190; 03121453001; 03051315001 or 05807875001 and 07963084190. Optional: 05527503001; 28127387001	CE-mark	Roche Diagnostics GmbH	Mannheim, Germany	05212294190: 48T/kit 03587797190: 5.1 liters	<a href="https://extranet.who.int/pgweb/content/public-report-cobasC2%AE-ampli-prep-cobasC2%AE-taqman%E2%84%A2-1-qualitative-test-version-20-taqman-48">https://extranet.who.int/pgweb/content/public-report-cobasC2%AE-ampli-prep-cobasC2%AE-taqman%E2%84%A2-1-qualitative-test-version-20-taqman-48</a>
2012	Virological Technologies	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 96)	05212294190; 03587797190; 03279332001; 03051315001; 07347308001 or 05807875001 and 07963084190. Optional: 05527503001; 28127387001	CE-mark	Roche Molecular Systems, Inc.	Branchburg, NJ, USA	05212294190: 48T/kit 03587797190: 5.1 liters	<a href="https://extranet.who.int/pgweb/content/public-report-cobasC2%AE-ampli-prep-cobasC2%AE-taqman%E2%84%A2-hiv-1-qualitative-test-version-20-taqman-96">https://extranet.who.int/pgweb/content/public-report-cobasC2%AE-ampli-prep-cobasC2%AE-taqman%E2%84%A2-hiv-1-qualitative-test-version-20-taqman-96</a>
2012	HIV RDT	HIV 1/2 STAT-PAK	HIV101	RoW	Chembio Diagnostic Systems Inc.	Site 1: Chembio Diagnostic Systems, Inc. (3661 Horseblock Road, Medford, Long Island, 11763, NY, USA) Site 2: Chembio Diagnostics Malaysia Sdn. Bhd. located at N-TATT Building 2nd floor, No. 2-1 Jalan TP5, Taman Perindustrian, UEP, 47600, Subang Jaya, Selangor, Malaysia	20T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-hiv-12-stat-pak%E2%84%A2-pqdx-0007-006-00">https://extranet.who.int/pgweb/content/public-report-hiv-12-stat-pak%E2%84%A2-pqdx-0007-006-00</a>
2011	Virological Technologies	NucliSENS EasyQ HIV-1 v2.0 (Automated)	280140; 280130; 280131; 280132; 280133; 280134; 285056; 200309; and 285033	CE-mark	bioMérieux SA	Marcy L'Etoile, France	280130, 280131, 280132, 280133 and 280134: 4x1L 285033: 48 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-nuclisens-easyq%E2%84%A2-hiv-1-v20-automated-pqdx-0127-016-00">https://extranet.who.int/pgweb/content/public-report-nuclisens-easyq%E2%84%A2-hiv-1-v20-automated-pqdx-0127-016-00</a>
2011	Virological Technologies	NucliSENS EasyQ HIV-1 v2.0 (Semi-Automated)	200305; 200293; 200292; 285056; 200309; and 285033	CE-mark	bioMérieux SA	Marcy L'Etoile, France	200293 and 200292: 48T/kit, 285033: 48 T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-nuclisens-easyq%E2%84%A2-hiv-1-v20-semi-automated-pqdx-0148-016-00">https://extranet.who.int/pgweb/content/public-report-nuclisens-easyq%E2%84%A2-hiv-1-v20-semi-automated-pqdx-0148-016-00</a>
2011	HIV RDT	# Determine HIV-1/2	7D2342; 7D2343; 7D2343SET and 7D2343SETS.	RoW	Abbott Diagnostics Medical Co., Ltd	Matsudo-shi, Chiba-ken, Japan	20T/kit; 100T/kit; 100T/kit; 100T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-alere-determine%E2%84%A2-hiv-12-pqdx-0033-013-00">https://extranet.who.int/pgweb/content/public-report-alere-determine%E2%84%A2-hiv-12-pqdx-0033-013-00</a>
2011	Virological Technologies	Abbott RealTime HIV-1 (Manual)	2G31 (2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-manual-pqdx-0146-027-00">https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-manual-pqdx-0146-027-00</a>

**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: 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
2011	Virological Technologies	# Abbott RealTime HIV-1 (m 2000sp)	2G31 (2G31-90 or 2G31-010, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; 04J71-93; and 9K14-02	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T) or 2G31-010 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit	<a href="https://extranet.who.int/pgweb/content/%E2%80%A2-public-report-abbott-realtime-hiv-1-m2000sp-pqdx-0145-027-00-pdf-1345mb">https://extranet.who.int/pgweb/content/%E2%80%A2-public-report-abbott-realtime-hiv-1-m2000sp-pqdx-0145-027-00-pdf-1345mb</a>
2011	Virological Technologies	Abbott RealTim e HIV-1 (m 24sp)	3N06-01, 2G31(2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93	CE-mark	Abbott Molecular Inc.	Des Plaines, IL, USA	2G31-90: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit	<a href="https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-m24sp-pqdx-0083-027-00">https://extranet.who.int/pgweb/content/public-report-abbott-realtime-hiv-1-m24sp-pqdx-0083-027-00</a>
2010	Malaria RDT	Bioline Malaria Ag P.f	05FK50; 05FK51; 05FK52; 05FK53	CE-mark	Abbott Diagnostics Korea Inc	Giheung-ku, Republic of Korea	25T/kit; 25T/kit; 1T/kit x 25 each; 1T/kit x 25 each.	<a href="https://extranet.who.int/pgweb/content/public-report-sd-bioline-malaria-ag-pf-and-sd-bioline-malaria-ag-pf-poct-pqdx-0031-012-01">https://extranet.who.int/pgweb/content/public-report-sd-bioline-malaria-ag-pf-and-sd-bioline-malaria-ag-pf-poct-pqdx-0031-012-01</a>

\*\* These products are subject to a WHO Notice of Concern: [https://www.who.int/diagnostics\\_laboratory/procurement/complaints/en/](https://www.who.int/diagnostics_laboratory/procurement/complaints/en/).  
 # The public reports were amended. Please view the public report to view the summary of the changes made on the public report and the product.

**The following product will be discontinued by 31 July 2024:**  
 BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount CD4 Reagent Kit (Absolute and Percentage CD4+ Counts)  
 BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (Absolute CD4+, CD8+, and CD3+ Counts)  
 BD FACSPresto Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and BD FACSPresto Cartridges Kit

**List of delisted Products**

Year delisted	Type of assay	Product name	Product code(s)	Manufacturer	Reason for Delisting
2021	HIV RDT	HIV 1/ 2 STAT-PAK Dipstick	HIV303	ChemBio Diagnostic Systems, Inc.	Withdrawal by the manufacturer.
2021	HCV Assay	Genedrive HCV ID Kit	ID-HCV-03	Genedrive Diagnostics Ltd	Failure to verify the claimed analytical Limit of detection (LoD).
2021	HIV Serology	VIKIA HIV 1/2	31112	BioMérieux SA	Withdrawal by the manufacturer.
2021	HBsAg Assay	VIKIA HBsAg	31124	BioMérieux SA	Withdrawal by the manufacturer.
2020	HCV Assay	bioelisa HCV 4.0	3000-1115 and 3000	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV Serology	bioelisa HIV 1+2 Ag/Ab	3000-1172 and 3000-1173	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HBsAg Assay	bioelisa HBsAg 3.0	3000-1158 and 3000-1159	Biokit S.A	Discontinuation of the product by the manufacturer.
2020	HIV RDT	First Response HIV 1-2-0 Card test	105FRC100, 105FRC60, 105FRC30, and 105FRC05	Premier Medical Corporation Private Limited	Discontinuation of the product by the manufacturer.
2019	Murex anti-HCV (version 4.0)	Genedrive HCV ID Kit	7F51-01 and 7F51-02	DiSorin South Africa (Pty) Ltd.	Withdrawal by the manufacturer.

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