

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 |
|-------------------|------------------------------|--|---|--------------------|---|--|--|
| 2023 | HCV RDT | First Response HCV Card Test | PI03FRC25, PI03FRC50, and PI03FRC100 | RoW | Premier Medical Corporation Private Limited | Premier Medical Corporation Ltd., at A1-302 and 3702 to 3705 and 3801 to 3805 W/2 and W/3, GIDC Sarigam 396155, Gujarat, India | 25 T/kit, 50 T/kit, 100 T/kit |
| 2023 | HIV NAT | cobas HIV-1/HIV-2 Qualitative nucleic acid test for use on the cobas 6800/8800 and cobas HIV-1/HIV-2 Qualitative Nucleic acid test for use on the cobas 5800/6800/8800 Systems | 078622113190, and 09040528190 | CE-marked | Roche Molecular Systems, Inc., | Roche Molecular Systems, Inc., located at 1080 US Hwy 202 South Branchburg Township, 8879, United States of America | 96 T/kit, 192 T/kit |
| 2023 | HCV RDT | HCV Hepatitis C Virus Rapid Test Device (Whole blood/Serum/Plasma) | IHC-402WA, IHC-402WB, IHC-402WC, and IHC-402WD | RoW | ABON Biopharm (Hangzhou) CO., LTD | Abon Biopharm (Hangzhou) CO.,LTD, located 198# 12th Street East, Economic and Technological Development Area, 310018 Hangzhou, China | 40 T/kit 25 T/kit 40 T/kit 25 T/kit |
| 2023 | HIV NAT | SAMBA II HIV-1 Qual Whole Blood Test | 4500-12 | CE-marked | Diagnostics for the Real World Ltd | Diagnostics for the Real World in San Jose, CA, USA | 12 T/kit |
| 2023 | HPV Virological Technologies | cobas HPV | 07460155190, 07460171190, 07002238190, 06997546190, 06997511190, 06997538190, 06997503190 | CE-marked | Roche Molecular Systems, Inc. | Branchburg, New Jersey, USA | 480 T/kit |
| 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 25 T/kit 100 T/kit |
| 2022 | HCV NAT | Xpert HCV VL Fingerstick | GXHCV-FS-CE-10 | CE-marked | Cepheid AB | Röntgenvägen 5, SE-171 54 Solna, Sweden | 10 T/kit |
| 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 |
| 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 |
| 2022 | HIV NAT | cobas HIV-1 Nucleic acid test for use on the cobas 4800 System | 08792992190, 06979572190, | CE-marked | Roche Diagnostics GmbH | Sandhofer Strasse 116, Mannheim, 68305 Germany | 120 T/kit; 10 Sets; |
| 2022 | HIV RDT for self-testing | Wondfo HIV Self-Test | W006P005S, W006P0059, and W006P0060 | RoW | Guangzhou Wondfo Biotech Co., Ltd | 8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China | 1 T/kit; 20 T/kit 100T/kit |

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| 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 |
| 2022 | HIV RDT | TrinScreen HIV | 5551100 | RoW | Trinity Biotech Manufacturing Ltd | 1 Southern Cross IDA Business Park in Bray, Ireland | 100 T/kit |
| 2021 | HCV NAT | # cobas HCV (Quantitative nucleic acid test for use on cobas S800/6800/8800 Systems) | 6997732190 09040765190 | CE-marked | Roche Molecular Systems, Inc. | Sandhofer Strasse 116, Mannheim, 68305 Germany | 96 T/kit 192 T/kit |
| 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 |
| 2020 | HIV NAT | # cobas HIV-1 Quantitative nucleic acid test for use on the cobas S800/6800/8800 Systems | 07000995190 09040803190 | CE-marked | Roche Molecular Systems, Inc. | Sandhofer Strasse 116, Mannheim, 68305 Germany | 96 T/kit 192 T/kit |
| 2020 | HIV RDT | # MERISCREEN HIV 1-2 WB | HVWRPD-01 HVWRPD-02 HVWRPD-06 HVWRPD-07 HVWRPD-08 HVWRPD-09 HVWRPD-10 HVWRPD-11 HVWRPD-12 | CE-marked | 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 25 T/kit 30 T/kit 40 T/kit 60 T/kit |
| 2020 | Malaria RDT | Paracheck Pf - Rapid Test for P. Falciparum Malaria Malaria Device (Ver. 3) | 302030025, 302030005, 302030010, 302030025, 302030100, 302030025(1T) | CE-marked | 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 |
| 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-marked | 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 |
| 2020 | CD4 Technologies | VISITECT CD4 Advanced Disease | A8376 | CE-marked | AccuBio Ltd | AccuBio Ltd located at Hillfoots Business, Village, Alva, FK12 5DQ United Kingdom. | 25 T/kit |

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| 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 |
| 2020 | Malaria RDT | parascreen - Rapid test for Malaria Pan/Pf | 503030025(1T) 503030010; 503030025; 503030050; 503030100 | CE-marked | 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 |
| 2020 | Malaria RDT | Falcivax - Rapid test for Malaria Pv/Pf | 503010025(1T) 503010010; 503010025; 503010050; 503010100 | CE-marked | 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 |
| 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 |
| 2020 | HCV NAT | Alinity m HCV | 08N50-090; 08N50-080; 08N50-070 | CE-marked | 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 |
| 2020 | Malaria RDT | STANDARD Q Malaria P.f/P.v Ag Test | 09MAL20D | CE-marked | SD Biosensor, Inc. | 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea | 25 T/kit |
| 2020 | Malaria RDT | STANDARD Q Malaria P.f Pan Ag Test | 09MAL30D | CE-marked | SD Biosensor, Inc. | 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea | 25 T/kit |
| 2020 | Malaria RDT | STANDARD Q Malaria P.f Ag Test | 09MAL10D | CE-marked | SD Biosensor, Inc. | 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea | 25 T/kit |
| 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 |
| 2020 | HCV EIA | Monolisa HCV Ag-Ab ULTRA V2 | 72561 and 72562 | CE-marked | Bio-Rad | 3, bd Raymond Poincaré, 92430, Marne La Coquette, France and Route de Cassel, 59114, Steenvoorde, France | 96 T/kit 480 T/kit |
| 2019 | HCV NAT | Abbott RealTime HCV | 4J86-90; 4J86-80; and 4J86-70 | CE-marked | Abbott Molecular Inc | 1300 East Touhy Avenue, Des Plaines, IL 60018 USA | 96 T/kit |

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| 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 | 02N09-092; and 02N09-080 | CE-marked | Abbott GmbH | Max-Planck-Ring 2, Wiesbaden, 65205, Germany | 96 T/ kit |
| 2019 | HIV RDT | First Response HIV 1-2.O 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 | 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 |
| 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, Gosen-shi, Niigata, Japan | 100 T/kit |
| 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, Leichhardt 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; |
| 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 |
| 2019 | HIV RDT | #ONE STEP Anti-HIV (1&2) Test | ITPW02152-TC40 ITPW02152-TC25 ITPW02153-TC40 ITPW02153-TC40SA 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 |

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| 2019 | Malaria RDT | #AdvDx Malaria Pf Rapid Malaria Ag Detection Test | 00-DKM-RK-MAL-ADX-004-001, 00-DKM-RK-MAL-ADX-004-025, 00-DKM-RK-MAL-ADX-004-010, and 00-DKM-RK-MAL-ADX-004-050 | 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 | 1 T/kit, 10 T/kit, 25 T/kit, 50 T/kit |
| 2019 | Malaria RDT | # NxTek Eliminate Malaria Pf and and NxTek Malaria Pf | 05FK140; 05FK141; 05FK142; 05FK143 | CE-marked | 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 | 25T/kit; 25T/kit; 1T/kit x 25 each; 1T/kit x 25 each |
| 2019 | HIV NAT | m-PIMA HIV-1/2 VL | 27015-W50 | RoW | Abbott Rapid Diagnostics Jena GmbH | Oriaweg 1, D-07743 Jena, Germany | 50 cartridges/kit |
| 2018 | Malaria RDT | First Response Malaria Antigen P. <i>falciparum</i> (HRP2) Card Test | PI13FRC25S; 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 × single kit; 10 × single kit; 25 × multi kit; 30 × multi kit |
| 2018 | Malaria RDT | First Response Malaria Ag. P.f. / P.v. Card Test | PI19FRC10S; PI19FRC25S; 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 | 10 × single test; 25 × single test; 30 × multi test; 25 × multi test |
| 2018 | Malaria RDT | Bioline Malaria Ag P.f/P.v | 05FK120; 05FK123 | CE-marked | Abbott Diagnostics Korea Inc | 65 Borahagal-ro, Giheung-gu, Yongin-si, Geonggi-do, South Korea | 25T/kit; 17/kit |
| 2018 | HIV RDT for self-testing | INSTI HIV Self Test | 90-1071 | RoW | bioLytical Laboratories Inc. | Richmond, British Columbia, Canada | 1T/kit |
| 2018 | HIV RDT | One Step HIV1/2 Whole Blood/Serum/Plasma Test | W006-CAP2, W006-P0045, W006-P0046, W006-P0047, W006-P0048, W006-CAP2-F, W006-P0049 | 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; |
| 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. |

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| 2018 | Malaria RDT | First Response Malaria Ag. pLDH/HRP2 Combo Card Test | PI16FRC10s PI16FRC25s PI16FRC25 PI16FRC30 | 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 |
| 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 |
| 2018 | HPV Virological Technologies | care HPV Test | 614015 | CE-marked | QIAGEN GmbH | site 1: QIAGEN Sciences, Germantown, 20874, United States site 2: QIAGEN Shenzhen Co., Shenzhen China | 96 T/kit |
| 2018 | HCV EIA | INNOTEST HCV Ab IV | 80068; 80330 | CE-marked | Fujirebio Europe NV | Ghent, Belgium | 192T/kit 480T/kit |
| 2017 | HBSAg RDT | Bioline HBSAg WB | 01FK10W | RoW | Abbott Diagnostics Korea Inc | Giheung-gu, Republic of Korea | 30T/kit |
| 2017 | HIV RDT | Genie Fast HIV 1/2 | 72327; 72347; 72330 | CE-marked | Bio-Rad | Marne La Coquette, France | 25T/kit 50T/kit 50T/kit |
| 2017 | HPV Virological Technologies | Xpert HPV | GXHPV-CE-10 | CE-marked | Cepheid AB | Solna, Sweden | 10T/kit |
| 2017 | HIV NAT | Aptima HIV-1 Quant Dx Assay | PRD-03000 (PRD-03002, PRD-03001); 303014; PRD-03003; and 303095 | CE-marked | Hologic, Inc. | San Diego, USA | 100T/kit |
| 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 the outer packaging (i.e. 5X4-1001.001, .002, ...). | RoW | OraSure Technologies, Inc. | site 1: Bethlehem, USA site 2: Phetchabun, Thailand site 3: Ayutthaya, Thailand | 50T/kit; 250T/kit; 110T/kit |
| 2017 | HIV NAT | Xpert HIV-1 Viral Load | GXHIV-VL-CE-10 | CE-marked | Cepheid AB | Solna, Sweden | 10T/kit |
| 2017 | HCV NAT | Xpert HCV Viral Load | GXHCV-VL-CE-10 | CE-marked | Cepheid AB | Solna, Sweden | 10T/kit |
| 2017 | HIV Confirmatory Assay | Genieus HIV 1/2 Confirmatory Assay with Genieus HIV1/2 Confirmatory Controls | 72460; and 72329 | CE-marked | Bio-Rad | Marnes-La-Coquette, France | 20T/kit |
| 2017 | HCV RDT | OraQuick HCV Rapid Antibody Test Kit | 1001-0270; 001-0274 | CE-marked | OraSure Technologies, Inc. | Bethlehem, USA | 25T/kit; 100T/kit |

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| 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 |
| 2016 | HCV RDT | Bioline HCV | 02FK10; 02FK16; 02FK17 | RoW | Abbott Diagnostics Korea Inc | Giheung-gu, Republic of Korea | 30T/kit 25T/kit 30T/kit |
| 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 |
| 2016 | HIV NAT | Xpert HIV-1 Qual Assay | GXHIV-QA-CE-10 | CE-marked | Cepheid AB | Solna, Sweden | 10 cartridges/kit and instrument |
| 2016 | HIV NAT | # m-PIMA HIV-1/2 Detect | 27011R050 27030R001 | CE-marked | Alere Technologies GmbH | Jena, Germany | 50 cartridges/kit Instrument |
| 2016 | HIV RDT | DPP HIV 1/2 Assay | 65-9506-0 | RoW | Chembio Diagnostic Systems Inc. | Medford, NY, USA | 20T/kit |
| 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 |
| 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-marked | RPC Diagnostics Systems | Nizhny Novgorod, Russia | 96T/kit; 192T/kit; 480T/kit; 96T/kit (for detection) or 48T/kit (for confirmation) 200T/kit |
| 2016 | HIV Confirmatory Assay | MP Diagnostics HIV Blot 2.2 | 11030-018; 11030-036 | CE-marked | MP Biomedicals Asia Pacific Pte.Ltd. | Singapore, Singapore | 18T/kit; 36T/kit |
| 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 |

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| 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; WJ-18510E; WJ-18510; WJ-18510E; WJ-18510E; WJ-18550E. | 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; 50 T/kit; 10 T/kit; 50 T/kit; 10 T/kit; 50 T/kit; 10 T/kit; 50 T/kit. |
| 2015 | CD4 Technologies | Aquios CL flow cytometer | B30166; B39101; B39102; B25697; B25698; B23536; B23538; B23533; B23534; B23535; B25700; and B23502 | CE-marked | Beckman Coulter Life Sciences | site 1: Miami, FL, USA (instrument site) site 2: Hialeah, FL, USA (reagent site) | 50T/kit |
| 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. |
| 2015 | Malaria RDT | Bioline Malaria Ag P.f/P.v | 05FK80; 05FK81; 05FK82; 05FK83; 05FK86; 05FK87 | CE-marked | Abbott Diagnostics Korea Inc | Giheung-gu, Republic of Korea | 25T/kit; 25T/kit 1T/kit x25 each 1T/kit x25 each 10T/kit 25T/kit |
| 2015 | Malaria RDT | Bioline Malaria Ag P.f (HRP2/pLDH) | 05FK90; 05FKF93; 05FK91; 05FK092 | CE-marked | Abbott Diagnostics Korea Inc | Giheung-gu, Republic of Korea | 25T/kit; 1T/kit x25 each 25T/kit 1T/kit x 25 each |
| 2015 | HCV EIA | INNO-LIA HCV Score | 80538 | CE-marked | Fujirebio Europe NV | Zwijnaarde, Belgium | 20T/kit |
| 2015 | HIV EIA | DS-EIA-HIV-AGAB-SCREEN | I-1654/1.2; I-1652/1.2; I-1656/1.2 | CE-marked | RPC Diagnostics Systems | Nizhny Novgorod, Russia | 96T/1 plate; 192T/2 plates; 480 T/5 plates |

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| 2015 | Malaria RDT | **CareStart Malaria HRP2/pLDH (Pf/PAN) COMBO | multi kit (product codes: RMRM-02571; RMRM-02571CB; RMRM-02571RB; RMRM-02571RI; RMRM-05071; RMRM-05071CB; RMRM-05071RB and RMRM-05071RI) single kit (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. |
| 2015 | Malaria RDT | **CareStart Malaria HRP2 (Pf) | multi kit (product codes: RMOM-02571; RMOM-02571CB; RMOM-02571RB; RMOM-02571RI; RMOM-05071; RMOM-05071CB; RMOM-05071RB and RMOM-05071RI) single kit (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; |
| 2015 | Malaria RDT | **CareStart Malaria HRP2/pLDH (Pf/Pv) COMBO | multi kit (product codes: RMVM-02571; RMVM-02571CB; RMVM-02571RB; RMVM-02571RI; RMVM-05071; RMVM-05071CB; RMVM-05071RB and RMVM-05071RI) single kit (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 |
| 2015 | Malaria RDT | **CareStart Malaria HRP2/pLDH (Pf) | multi kit (product codes: RMPM-02571; RMPM-02571CB; RMPM-02571RB; RMPM-02571RI; RMPM-05071; RMPM-05071CB; RMPM-05071RB and RMPM-05071RI) single kit (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 |
| 2015 | Malaria RDT | **CareStart Malaria pLDH (PAN) | multi kit (product codes: RMNM-02571; RMNM-02571CB; RMNM-02571RB; RMNM-02571RI; RMNM-05071; RMNM-05071CB; RMNM-05071RB and RMNM-05071RI) | RoW | Access Bio, Inc. | Somerset NJ, USA | 25T/kit; 50T/kit |
| 2015 | HIV Confirmatory Assay | INNO-Lia HIV I/II Score | 80540 | CE-marked | Fujirebio Europe NV | Ghent, Belgium | 20T/kit |
| 2015 | HIV EIA | Murex HIV Ag/Ab Combination | 7G79-09 (GE41, 96 wells); and 7G79-11 (GE42, 480 wells) | CE-marked | DiaSorin S.p.A UK Branch | Dartford, UK | 96T/kit; 480T/kit |
| 2014 | HIV NAT | COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 48) | 06693083190; 03051315001; 03279332001; 03587797190; 06989861190; 05807875001; 03516440001; and 28127387001 | CE-marked | Roche Molecular Systems, Inc. | Branchburg, New Jersey, USA | 48T/kit |
| 2014 | HIV NAT | COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (TaqMan 96) | 06693083190; 03587797190; 06989861190; 03051315001; 03121453001; 28127387001; 05807875001; and 03516440001 | CE-marked | Roche Diagnostics GmbH | Mannheim, Germany | 48T/kit |

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 |
|-------------------|------------------|--|--|--------------------|---|------------------------------------|---|
| 2014 | HIV RDT | SURE CHECK HIV 1/2 Assay | HIV201 (60-9527-0), | RoW | Chembio Diagnostic Systems Inc. | Medford, NY, USA | 25T/kit |
| 2014 | HBSAg EIA | Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3 | 9F80-01; 9F80-05; 2G27-01 | CE-marked | DiaSorin S.p.A UK Branch | Dartford, UK | 96T/kit; 480T/kit 50T/kit |
| 2014 | Malaria RDT | ParaHIT f Ver. 1.0 Rapid Test for P.falciparum Malaria Device | 55IC104-10; 55IC104-25; 55IC104-50 | CE-marked | ARKRAY Healthcare Pvt. Ltd. | Sachin (Surat), India | 10T/kit; 25T/kit; 50T/kit |
| 2014 | CD4 Technologies | BD FACSPresto Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and BD FACSPresto Cartridges Kit | 651000; 657681; 655495 | CE-marked | Becton, Dickinson and Company, BD Biosciences | San Jose, California, USA | 651000: instrument 657681: cartridge (100/box) 655495: pipette (100/box) |
| 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, | RoW | ABON Biopharm (Hangzhou) Co. Ltd. | Hangzhou, PR China | 40T/kit; 40T/kit; 40T/kit; 40T/kit; 10T/kit; 40T/kit |
| 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 swabs); 48T/kit with no support materials; |
| 2013 | Malaria RDT | Bioline Malaria Ag P.f/Pan | 05FK60; 05FK61; 05FK62; 05FK63; 05FK67 | CE-marked | Abbott Diagnostics Korea Inc | Giheung-gu, Republic of Korea | 25T/kit; 25x1T/kit; 1T/kit; 25T/kit; 30T/kit |
| 2013 | HIV NAT | Abbott RealTime HIV-1 Qualitative (Manual) | 4N66-90; 4N66-80; 6K12-24; 9K15-01; 4N66-01; and 4N66-66 (optional) | CE-marked | Abbott Molecular Inc. | Des Plaines, IL, USA | 96T/kit; 4x24T pack |
| 2013 | HIV NAT | Abbott RealTime HIV-1 Qualitative (m 2000sp) | 4N66-90; 9K14-02; 9K15-01; 4N66-80; 4N66-01; 6K12-24; and 4N66-66 (optional) | CE-marked | Abbott Molecular Inc. | Des Plaines, IL, USA | 96T/kit; 4x24T pack |
| 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 |

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 |
|-------------------|------------------|--|--|--------------------|---|---|--|
| 2013 | HIV EIA | Genscreen ULTRA HIV Ag-Ab | 72386; and 72388 | CE-marked | Bio-Rad | Marnes La Coquette, France | 96T/kit; 480T/kit |
| 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 |
| 2012 | CD4 Technologies | Pima CD4 Test | 260100025 and 260300003; 260100100; and 260300003 | CE-marked | Abbott Rapid Diagnostics Jena GmbH | Orlweg 1, D-07743 Jena, Germany | 25 cartridges/kit and instrument; 100 cartridges/kit and instrument |
| 2012 | CD4 Technologies | BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount Reagent Kit (<i>Absolute CD4+</i> , <i>CD8+</i> , and <i>CD3+ Counts</i>) | 337858; 340166; 340167 | CE-marked | Becton, Dickinson and Company, BD Biosciences | San Jose, CA, USA | 337858: instrument system 340166: 25T/kit 340167: 50T/kit |
| 2012 | CD4 Technologies | BD FACSCount Instrument System with FACSCount Control Kit and BD FACSCount CD4 Reagent Kit (<i>Absolute and Percentage CD4+ Counts</i>) | 337858; 340166; 339010 | CE-marked | Becton, Dickinson and Company, BD Biosciences | San Jose, CA, USA and Cayey, Puerto Rico | 337858: instrument system 340166: 25T/kit 339010: 50T/kit |
| 2012 | HIV NAT | COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 48) | 05212294190; 03587797190; 03121453001; 03051315001 or 05807875001 and 07963084190. Optional: 05527503001; 28127387001 | CE-marked | Roche Diagnostics GmbH | Mannheim, Germany | 05212294190: 48T/kit 03587797190: 5.1 liters |
| 2012 | HIV NAT | 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-marked | Roche Molecular Systems, Inc. | Branchburg, NJ, USA | 05212294190: 48T/kit 03587797190: 5.1 liters |
| 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 |
| 2011 | HIV NAT | NucliSENS EasyQ HIV-1 v2.0 (Automated) | 280140; 280130; 280131; 280132; 280133; 280134; 285056; 200309; and 285033 | CE-marked | bioMérieux SA | Marcy L'Etoile, France | 280130, 280131, 280132, 280133 and 280134: 4x1L 285033: 48 T/kit |

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 |
|-------------------|---------------|---|--|--------------------|-------------------------------------|-------------------------------|--|
| 2011 | HIV NAT | NucliSENS EasyQ HIV-1 v2.0 (Semi-Automated) | 200305; 200293; 200292; 285056; 200309; and 285033 | CE-marked | bioMérieux SA | Marcy L'Etoile, France | 200293 and 200292: 48T/kit, 285033: 48 T/kit |
| 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 |
| 2011 | HIV NAT | Abbott RealTime HIV-1 (Manual) | 2G31 (2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93 | CE-marked | 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 |
| 2011 | HIV NAT | 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-marked | 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 |
| 2011 | HIV NAT | Abbott RealTime 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-marked | 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 |
| 2010 | Malaria RDT | Bioline Malaria Ag P.f | 05FK50; 05FK51; 05FK52; 05FK53 | CE-marked | Abbott Diagnostics Korea Inc | Giheung-ku, Republic of Korea | 25T/kit; 25T/kit; 1T/kit x 25 each; 1T/kit x 25 each. |

** These products are subject to a WHO Notice of Concern: 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 |
|---------------|-----------------------|---|-----------------------------|------------------------------------|--|
| 2023 | HIV Nucleic Acid Test | cobas HIV-1 Quantitative nucleic acid test for use on the cobas 4800 System | 06979599190 and 06979572190 | Roche Diagnostics GmbH | Discontinuation of the product by the manufacturer. |
| 2023 | HIV Nucleic Acid Test | m-PIMA HIV-1/2 Detect | 27011-W50 and 27011R010 | Abbott Rapid Diagnostics Jena GmbH | Discontinuation of the RoW regulatory version. The CE-marked regulatory version is maintained as prequalified. |
| 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). |

WHO list of prequalified in vitro diagnostic products

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| Year prequalified | Type of assay | Product name | Product code(s) | Manufacturer | Reason for Delisting |
|-------------------|---------------|---|---|---|--|
| 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 | I05FRC100, I05FRC60, I05FRC30, and I05FRC05 | Premier Medical Corporation Private Limited | Discontinuation of the product by the manufacturer. |
| 2019 | HCV Assay | Murex anti-HCV (version 4.0) | 7F51-01 and 7F51-02 | DiaSorin South Africa (Pty) Ltd. | Withdrawal by the manufacturer. |
| 2019 | HIV EIA | Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost/TMB | OPKR035, OPKR035, OPKR055(Q), and OUV175 | Siemens Healthcare Diagnostics Products GmbH | Siemens Healthcare Diagnostics Products GmbH |
| 2019 | HBsAg Assay | Enzygnost HBsAg 6.0 and Supplementary reagents kit for Enzygnost/TMB | OPIH035 and OPIH055 | Siemens Healthcare Diagnostics Products GmbH | Siemens Healthcare Diagnostics Products GmbH |
| 2018 | HIV RDT | SD Bioline HIV Ag/Ab Combo | 03FK30 and 03FK35 | Abbott Diagnostics Korea Inc. (Formerly Standard Diagnostics, Inc.) | Discontinuation of the product by the manufacturer. |
| 2017 | Malaria RDT | ParaHIT f Ver. 1.0 Rapid Test for P. Falciparum Malaria Dipstick | 55IC103-10, 55IC103-25 and 55IC103-50 | Arkray Healthcare Private Limited | Failure to meet product testing acceptance criteria. |

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