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<th>Packaging</th>
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<td>2020</td>
<td>HCV NAT</td>
<td>Alinity m HCV</td>
<td>08N50-090; 08N50-080; 08N50-070</td>
<td>CE-mark</td>
<td>Abbott Molecular Inc</td>
<td>1300 East Touhy Avenue, Des Plaines, IL 60018 USA</td>
<td>4 trays of 48 T/kit 12 tubes of each control 4 tubes x 1.95 mL</td>
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<td>STANDARD Q Malaria P.f/P.v Ag Test</td>
<td>09MAL20D</td>
<td>CE-mark</td>
<td>SD Biosensor, Inc.</td>
<td>74, Osongsaengmyeong 4-ro, Osong-eup, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea</td>
<td>25 T/kit</td>
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<td>Malaria RDT</td>
<td>STANDARD Q Malaria P.f Pan Ag Test</td>
<td>09MAL30D</td>
<td>CE-mark</td>
<td>SD Biosensor, Inc.</td>
<td>74, Osongsaengmyeong 4-ro, Osong-eup, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea</td>
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<tr>
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<td>STANDARD Q Malaria P.f Ag Test</td>
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<td>SD Biosensor, Inc.</td>
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<td>STANDARD Q HCV Ab Test</td>
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<td>RoW</td>
<td>SD Biosensor, Inc.</td>
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<td>HCV EIA</td>
<td>Monolisa HCV Ag-Ab ULTRA V2</td>
<td>72561 and 72562</td>
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<td>Bio-Rad</td>
<td>3, bd Raymond Poincaré, 92430, Marne La Coquette, France and Route de Cassel, 59114, Steenvoorde, France</td>
<td>96 T/kit 480 T/kit</td>
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<td>2019</td>
<td>HCV NAT</td>
<td>Abbott RealTime HCV</td>
<td>4J86-90; 4186-80; and 4186-70</td>
<td>CE-mark</td>
<td>Abbott Molecular Inc</td>
<td>1300 East Touhy Avenue, Des Plaines, IL 60018 USA</td>
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<td>HIV RDT for self-testing</td>
<td>SURE CHECK HIV Self-Test</td>
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<td>Chembio Diagnostic Systems, Inc</td>
<td>1661 Horseblock Road, Medford, NY 11763 USA</td>
<td>1 T/kit</td>
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<td>2019</td>
<td>HPV Virological Technologies</td>
<td>Abbott RealTime High Risk HPV</td>
<td>02N09-092; and 02N09-080</td>
<td>CE-mark</td>
<td>Abbott GmbH &amp; Co.KG</td>
<td>Max Planck-Ring 2, Wiesbaden, 65205, Germany</td>
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<td>2019</td>
<td>HIV RDT</td>
<td>First Response HIV 1-2.0 Card test (Version 2.0)</td>
<td>P105FRC25; P105FRC30; P105FRC50; P105FRC60; P105FRC100</td>
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<td>Premier Medical Corporation Private Limited</td>
<td>A1-302, GIDC, Sarigam, India</td>
<td>25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit</td>
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<td>HBsAg RDT</td>
<td>*Determine HBsAg 2</td>
<td>7D2942; 7D2943; 7D2943 SET</td>
<td>CE-mark</td>
<td>Alere Medical Co. Ltd</td>
<td>557 Matsushidai, Matsudo-shi, 270-2214, Chiba-ken, Japan</td>
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<td>HCV EIA</td>
<td>ARCHITECT HCV Ag assay</td>
<td>6L47-29; 6L47-11; 6L47-02; and 8C89-01</td>
<td>CE-mark</td>
<td>Denka Seiken Co., LTD, Kagamida Factory</td>
<td>Street 1359-1, Kagamida, Kigoshi, Gosen-shi, Nigata, Japan</td>
<td>100 T/kit</td>
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</table>
## 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: 24 April 2020

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<th>Packaging</th>
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<tr>
<td>2019</td>
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<td>*Mylan HIV Self Test</td>
<td>ARST001-03</td>
<td>RoW</td>
<td>Atomo Diagnostics Pty Ltd</td>
<td>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 &amp; 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Muizenberg, 7945, South Africa</td>
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<td>HIV/HIV/CT RDT</td>
<td>*First Response® HIV1+2/Syphilis Combo Card Test</td>
<td>I20FRC25; I20FRC30; I20FRC50; I20FRC60; I20FRC100</td>
<td>RoW</td>
<td>Premier Medical Corporation Private Limited</td>
<td>Sarigam, Gujarat, India</td>
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<td>HIV RDT</td>
<td>*ONE STEP Anti-HIV (1&amp;2) Test</td>
<td>ITPW02152-TC40; ITPW02152-TC25; ITPW02153-TC40; ITPW02153-TC40SA</td>
<td>RoW</td>
<td>InTec PRODUCTS, INC</td>
<td>808, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China</td>
<td>40 T/kit</td>
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<td>Rapid Anti-HCV Test</td>
<td>ITPW01152-TC40; ITPW01152-TC25; ITPW01153-TC40</td>
<td>RoW</td>
<td>InTec PRODUCTS, INC</td>
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<td>40 T/kit</td>
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<td>*m-PIMA HIV-1/2 VL</td>
<td>27015-W50</td>
<td>RoW</td>
<td>Alere Technologies GmbH</td>
<td>Luebstedter Str. 103-105, Jena, Thueringia, 07749, Germany</td>
<td>50 cartridges/kit</td>
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<tr>
<td>Year</td>
<td>Type of assay</td>
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<td>Packaging</td>
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<tr>
<td>2018</td>
<td>Malaria RDT</td>
<td>First Response® Malaria Antigen P. falciparum (HRP2) Card Test</td>
<td>PI13FRC25s; PI13FRC10s; PI13FRC25; PI13FRC30</td>
<td>RoW</td>
<td>Premier Medical Corporation Limited</td>
<td>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</td>
<td>25 x single kit; 10 x single kit; 25 x multi kit; 30 x multi kit</td>
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<tr>
<td>2018</td>
<td>Malaria RDT</td>
<td>First Response® Malaria Ag. Pf/pLDH/HRP2 Combo Card Test</td>
<td>PI16FRC10s; PI16FRC25s; PI16FRC25; PI16FRC30</td>
<td>RoW</td>
<td>Premier Medical Corporation Limited</td>
<td>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</td>
<td>10 x single kit; 25 x multi kit; 30 x multi kit</td>
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<tr>
<td>2018</td>
<td>Malaria RDT</td>
<td>First Response®/Malaria Ag. P.f./p. v. Card Test</td>
<td>PI19FRC10s; PI19FRC25s; PI19FRC30; PI19FRC25</td>
<td>RoW</td>
<td>Premier Medical Corporation Limited</td>
<td>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</td>
<td>10 x single test; 25 x single test; 30 x multi test; 25 x test</td>
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<tr>
<td>2018</td>
<td>Malaria RDT</td>
<td>5D BIOLINE Malaria Ag P.f/P.v Card Test</td>
<td>05FK120; 05FK123</td>
<td>CE-mark</td>
<td>Standard Diagnostics, Inc.</td>
<td>65 Borahagal-ro, Giheung-gu, Yongin-si, Geonjido, South Korea</td>
<td>250T/kit; 17/kit</td>
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<td>2018</td>
<td>HIV RDT for self-testing</td>
<td>*INSTI® HIV Self Test</td>
<td>90-1071</td>
<td>RoW</td>
<td>biolytical Laboratories Inc.</td>
<td>Richmond, British Columbia, Canada</td>
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<td>HIV RDT</td>
<td>One Step HIV1/2 Whole Blood/Serum/Plasma Test</td>
<td>W006-C4P2; W006-C4P2-F</td>
<td>RoW</td>
<td>Guangzhou Wondfo Biotech Co., Ltd</td>
<td>8 Lishizhan Road, Science City, Luogang District, Guangzhou, 510663, Republic of China</td>
<td>250T/kit; 407/kit</td>
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<td>2018</td>
<td>Malaria RDT</td>
<td>*One step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag</td>
<td>MFURPD-02; MFURPD-03; MFURPD-04</td>
<td>CE-marked</td>
<td>Meril Diagnostics Pvt. Ltd.</td>
<td>01-D3, Meril Park, Survey No. 135/2/B &amp; 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India</td>
<td>307/kit; 257/kit; 507/kit</td>
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<tr>
<td>2018</td>
<td>CD4 Technologies</td>
<td>*CyFlow® Counter System with CD4 easy count kit and CD4N easy count kit</td>
<td>CY-S-3022; 05-8401; and 05-8405</td>
<td>CE-marked</td>
<td>Sysmex Partec GmbH</td>
<td>site 1: Arndstr. 11a-b, 02826 Göttingen, Germany; and site 2: Exbio Praha a.s., Nad Safinou II 341, 252 50 Vestec, Czech Republic</td>
<td>100 T/kit</td>
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</table>
### WHO list of prequalified in vitro diagnostic products

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*Last update: 24 April 2020*

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<th>Packaging</th>
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<td>Vikia HBsAg</td>
<td>31124</td>
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<td>bioMérieux SA</td>
<td>376 Chemin de l'Orme, Marcy l'Etoile, 69280 France</td>
<td>25 T/kit</td>
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</tbody>
</table>
| 2018              | HPV Virological Technologies | core 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 |
| 2018              | HCV EIA       | INNOTEST HCV Ab IV | 80068; 80330   | CE-mark            | Fujirebio Europe NV | Ghent, Belgium | 192T/kit  
|                   |               |               |                 |                    |              | 480T/kit              |           |
| 2017              | HBsAg RDT     | SD BIOLINE HBsAg WB | 01FK10W       | RoW                | Standard Diagnostics, Inc. | Giheung-gu, Republic of Korea | 30T/kit   |
| 2017              | HIV RDT       | Genie™ Fast HIV 1/2 | 72327; 72347; 72330 | CE-mark            | Bio-Rad     | Marne La Coquette, France | 25T/kit   
<p>|                   |               |               |                 |                    |              | 50T/kit               | 50T/kit   |
| 2017              | Virological Technologies | Xpert HPV | GXHPV-CE-10     | CE-mark            | Cepheid AB  | Solna, Sweden         | 10T/kit   |
| 2017              | Virological Technologies | Aptima™ HIV-1 Quant Dx Assay | PRD-03000; PRD-03002; PRD-03001; PRD-03003; PRD-03009 | CE-mark            | Hologic, Inc. | San Diego, USA | 100T/kit   |
| 2017              | HIV RDT for self-testing | *OraQuick HIV Self-Test | 5X4-1000; 5X4-1001; 5X4-2001 | RoW                | OraSure Technologies, Inc. | Bethlehem, USA | 50T/kit; 250T/kit; 110T/kit |
| 2017              | Virological Technologies | *Xpert® HIV-1 Viral Load | GXHV-CE-10     | CE-mark            | Cepheid AB  | Solna, Sweden         | 10T/kit   |
| 2017              | HCV NAT       | *Xpert® HCV Viral Load | GXHCV-CE-10    | CE-mark            | Cepheid AB  | Solna, Sweden         | 10T/kit   |
| 2017              | HIV Confirmatory Assay | Geenius™ HIV 1/2 Confirmatory Assay with Geenius™ HIV1/2 Confirmatory Controls | 72460; 72329 | CE-mark            | Bio-Rad     | Marnes-La-Coquette, France | 20T/kit   |
| 2017              | HCV RDT       | OraQuick HCV Rapid Antibody Test Kit | 1001-0270; 001-0274 | CE-mark            | OraSure Technologies, Inc. | Bethlehem, USA | 25T/kit; 100T/kit |</p>
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<th>Packaging</th>
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<td>HIV RDT</td>
<td>Diagnostic kit for HIV (1+2) antibody (colloidal gold)</td>
<td>R-401-50-C-2; KH-R-02; and A-GOLD-01</td>
<td>RoW</td>
<td>Shanghai Kehua Bio-engineering Co., Ltd</td>
<td>Shanghai, PR China</td>
<td>50T/kit</td>
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<td>2016</td>
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<td>*SD BIOLINE HCV</td>
<td>02FK10; 02FK16; 02FK17</td>
<td>RoW</td>
<td>Standard Diagnostics, Inc.</td>
<td>Gyeong-gu, Republic of Korea</td>
<td>30T/kit</td>
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<td>Alere™ HIV Combo</td>
<td>7D2842; 7D2843; 7D2843SET</td>
<td>RoW</td>
<td>Alere Medical Co. Ltd.</td>
<td>Matsudo-shi, Chiba-ken, Japan</td>
<td>20T/kit; 100T/kit; 100T/kit</td>
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<td>*Xpert® HIV-1 Qual Assay</td>
<td>GHIV-QA-CE-10</td>
<td>CE-mark</td>
<td>Cepheid AB</td>
<td>Solna, Sweden</td>
<td>10 cartridges/kit and instrument</td>
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<td>*m-PIMA HIV-1/2 Detect</td>
<td>270110050; 270110010; 270300001</td>
<td>CE-mark</td>
<td>Alere Technologies GmbH</td>
<td>Jena, Germany</td>
<td>50 cartridges/kit 50 cartridges/kit Instrument</td>
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<td>DPP® HIV 1/2 Assay</td>
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<td>Chembio Diagnostic Systems Inc.</td>
<td>Medford, NY, USA</td>
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<td>*OraQuick HIV 1/2 Rapid Antibody Test</td>
<td>5x-0010; 5x-0014; 5x-0062; 5x-0012; 5x-0015</td>
<td>RoW</td>
<td>OraSure Technologies, Inc.</td>
<td>site 1: Bethlehem, USA and site 2: Petchabun, Thailand</td>
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<td>*DS-EIA-HBsAg-0,01</td>
<td>B-1254/1.2; B-1252/1.2; B1255/1.2; B-1256/1.2; B-231/1.2</td>
<td>CE-mark</td>
<td>RPC Diagnostics Systems</td>
<td>Nizhniy Novgorod, Russia</td>
<td>967/kit; 967/kit (for detection) or 48T/kit (for confirmation) 200T/kit</td>
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<td>HIV Confirmatory Assay</td>
<td>MP Diagnostics HIV Blot 2.2</td>
<td>11030-018; 11030-036</td>
<td>CE-mark</td>
<td>MP Biomedical Asia Pacific Pte. Ltd.</td>
<td>Singapore, Singapore</td>
<td>18T/kit; 36T/kit</td>
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<td>HIV EIA</td>
<td>AiD™ anti-HIV 1+2 ELISA</td>
<td>W1-4896; W1-48480</td>
<td>RoW</td>
<td>Beijing Wantai Biological Pharmacy Enterprise Co.</td>
<td>Beijing, China</td>
<td>967/kit; 480T/kit</td>
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<td>Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)</td>
<td>W1-1810; W1-1810E; W1-1850; W1-1850E</td>
<td>RoW</td>
<td>Beijing Wantai Biological Pharmacy Enterprise Co.</td>
<td>Beijing, China</td>
<td>10T/kit w/accessories; 10T/kit; 257/kit; 507/kit</td>
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<td>CD4 Technologies</td>
<td>Aquios CL flow cytometer</td>
<td>B30266; B39101; B25697; B25698; B23536; B23538; B23533; B23534; B23535; B25700; and B23502</td>
<td>CE-mark</td>
<td>Beckman Coulter Life Sciences</td>
<td>site 1: Miami, FL, USA (instrument site) site 2: Hialeah, FL, USA (reagent site)</td>
<td>50T/kit</td>
</tr>
<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td>SD BIOLINE Malaria Ag P.f/P.v</td>
<td>D5FK80; D5FK81; D5FK82; D5FK83; D5FK86; D5FK87</td>
<td>CE-mark</td>
<td>Standard Diagnostics, Inc.</td>
<td>Giheung-gu, Republic of Korea</td>
<td>25T/kit; 25T/kit</td>
</tr>
<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td>SD BIOLINE Malaria Ag P.f (HRP2/pLDH)</td>
<td>D5FK90; D5FK93; D5FK91; D5FK92</td>
<td>CE-mark</td>
<td>Standard Diagnostics, Inc.</td>
<td>Giheung-gu, Republic of Korea</td>
<td>25T/kit; 1T/kit x 25 each 25T/kit</td>
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<tr>
<td>2015</td>
<td>HCV EIA</td>
<td>INNO-LIA HCV Score</td>
<td>80538</td>
<td>CE-mark</td>
<td>Fujirebio Europe NV</td>
<td>Zwijnaarde, Belgium</td>
<td>20T/kit</td>
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<tr>
<td>2015</td>
<td>HIV EIA</td>
<td>*DS-EIA-HIV-AGAB-SCREEN</td>
<td>I-1654/1.2; I-1652/1.2; I-1656/1.2</td>
<td>CE-mark</td>
<td>RPC Diagnostics Systems</td>
<td>Nizhny Novgorod, Russia</td>
<td>96T/1 plate; 192T/2 plates; 480 T/5 plates</td>
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<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td>**CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO</td>
<td>multi kit (product codes: RMRM-02571; RMRM-02571CB; RMRM-02571RB; RMRM-02571RI; RMRM-05071; RMRM-05071CB; RMRM-05071RB and RMRM-05071RI)</td>
<td>RoW</td>
<td>Access Bio, Inc.</td>
<td>Somerset NJ, USA</td>
<td>25T/kit; 50T/kit; 25T/kit; 40T/kit;</td>
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<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td>**CareStart™ Malaria HRP2 (Pf)</td>
<td>multi kit (product codes: RPMO-02571; RPMO-02571CB; RPMO-02571RB; RPMO-02571RI; RPMO-05071; RPMO-05071CB; RPMO-05071RB and RPMO-05071RI)</td>
<td>RoW</td>
<td>Access Bio, Inc.</td>
<td>Somerset NJ, USA</td>
<td>25T/kit; 50T/kit; 25T/kit; 40T/kit;</td>
</tr>
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</table>
## 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: 24 April 2020

<table>
<thead>
<tr>
<th>Year prequalified</th>
<th>Type of assay</th>
<th>Product name</th>
<th>Product code(s)</th>
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<th>Manufacturer</th>
<th>Manufacturing site(s)</th>
<th>Packaging</th>
</tr>
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<tbody>
<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td><strong>CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO</strong></td>
<td>multi kit (product codes: RMVM-02571; RMVM-02571CB; RMVM-02571RB; RMVM-02571RI; RMVM-05071; RMVM-05071CB; RMVM-05071RB and RMVM-05071RI)</td>
<td>RoW</td>
<td>Access Bio, Inc.</td>
<td>Somerset NJ, USA</td>
<td>25T/kit; 50T/kit</td>
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<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td><strong>CareStart™ Malaria HRP2/pLDH (Pf)</strong></td>
<td>multi kit (product codes: RMPM-02571; RMPM-02571CB; RMPM-02571RB; RMPM-02571RI; RMPM-05071; RMPM-05071CB; RMPM-05071RB and RMPM-05071RI)</td>
<td>RoW</td>
<td>Access Bio, Inc.</td>
<td>Somerset NJ, USA</td>
<td>25T/kit; 50T/kit</td>
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<tr>
<td>2015</td>
<td>Malaria RDT</td>
<td><strong>CareStart™ Malaria pLDH (PAN)</strong></td>
<td>multi kit (product codes: RMNM-02571; RMNM-02571CB; RMNM-02571RB; RMNM-02571RI; RMNM-05071; RMNM-05071CB; RMNM-05071RB and RMNM-05071RI)</td>
<td>RoW</td>
<td>Access Bio, Inc.</td>
<td>Somerset NJ, USA</td>
<td>25T/kit; 50T/kit</td>
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<td>2015</td>
<td>HIV Confirmatory Assay</td>
<td>INNO-Lia HIV I/II Score</td>
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<td>CE-mark</td>
<td>Fujirebio Europe NV</td>
<td>Ghent, Belgium</td>
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<td>2015</td>
<td>HIV EIA</td>
<td>Murex HIV Ag/Ab Combination</td>
<td>7G79-09 (GE41, 96 wells); and 7G79-11 (GE42, 480 wells)</td>
<td>CE-mark</td>
<td>DiaSorin S.p.A UK Branch</td>
<td>Dartford, UK</td>
<td>96T/kit; 480T/kit</td>
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<tr>
<td>2014</td>
<td>Virological Technologies</td>
<td>*COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 48)</td>
<td>0669308190; 03051315001; 03279332001; 0338779190; 06989861190; 05807875001; 03516440001; and 28127387001</td>
<td>CE-mark</td>
<td>Roche Molecular Systems, Inc.</td>
<td>Branchburg, New Jersey, USA</td>
<td>48T/kit</td>
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<tr>
<td>2014</td>
<td>Virological Technologies</td>
<td>*COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 96)</td>
<td>0669308190; 0358779190; 06989861190; 03051315001; 03121453001; 28127387001; 05807875001; and 03516440001</td>
<td>CE-mark</td>
<td>Roche Diagnostics GmbH</td>
<td>Mannheim, Germany</td>
<td>48T/kit</td>
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<tr>
<td>2014</td>
<td>HIV RDT</td>
<td>*SURE CHECK® HIV 1/2 Assay</td>
<td>HIV201 (60-9527-O),</td>
<td>RoW</td>
<td>Chembio Diagnostic Systems Inc.</td>
<td>Medford, NY, USA</td>
<td>25T/kit</td>
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<tr>
<td>Year prequalified</td>
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<tr>
<td>2014</td>
<td>HBsAg EIA</td>
<td>Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3</td>
<td>9FBD-01; 9FBD-09; 2027-01</td>
<td>CE-mark</td>
<td>DiaSorin S.p.A UK Branch</td>
<td>Dartford, UK</td>
<td>96T/kit; 480T/kit; 504T/kit</td>
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<tr>
<td>2014</td>
<td>Malaria RDT</td>
<td>ParaHIT f Ver. 1.0 Rapid Test for P.falciparum Malaria Device</td>
<td>55C104-10; 55C104-25; 55C104-50</td>
<td>CE-mark</td>
<td>ARKRAY Healthcare Pvt. Ltd.</td>
<td>Sachin (Surat), India</td>
<td>10T/kit; 25T/kit; 50T/kit</td>
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<tr>
<td>2014</td>
<td>CD4 Technologies</td>
<td>*BD FACSPresto™ Near-Patient CD4 Counter with BD CD4/CD8/SDI Cartridge and BD FACSPresto™ Cartridge Kit</td>
<td>651000; 657681; 655495</td>
<td>CE-mark</td>
<td>Becton, Dickinson and Company, BD Biosciences</td>
<td>San Jose, California, USA Singapore, Singapore</td>
<td>651000: instrument 657681: cartridge (100/box) 655495: pipette (100/box)</td>
</tr>
<tr>
<td>2013</td>
<td>HIV RDT</td>
<td>VIKIA HIV 1/2</td>
<td>31112</td>
<td>CE-mark</td>
<td>bioMérieux SA</td>
<td>Marcy L’Etoile, France</td>
<td>257T/kit</td>
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<tr>
<td>2013</td>
<td>HIV RDT</td>
<td>*INSTI HIV-1/2 Antibody Test</td>
<td>90-1013; 90-1010; 90-1022; 90-1021</td>
<td>RoW</td>
<td>BioLytical Laboratories, Inc.</td>
<td>Richmond, British Columbia, Canada</td>
<td>247T/kit; 247T/kit with support materials; 487T/kit; 487T/kit with support materials</td>
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<tr>
<td>2013</td>
<td>Malaria RDT</td>
<td>SD BIOLINE Malaria Ag.P/Pan SD BIOLINE Malaria Ag.P/Pan (POCT)</td>
<td>05F660; 05F661; 05F662; 05F663; 05F667</td>
<td>RoW</td>
<td>Standard Diagnostics, Inc.</td>
<td>Giheung-gu, Republic of Korea</td>
<td>257T/kit; 257T/kit; 17T/kit; 257T/kit; 307T/kit</td>
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<td>2013</td>
<td>Virological Technologies</td>
<td>*Abbott RealTime HIV-1 Qualitative (m 2000sp)</td>
<td>4N66-90; 9K15-02; 9K15-01; 4N66-80; 4N66-01; 6K12-24; and 4N66-66 (optional)</td>
<td>CE-mark</td>
<td>Abbott Molecular Inc.</td>
<td>Des Plaines, IL, USA</td>
<td>96T/kit; 4x24T pack</td>
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<tr>
<td>2013</td>
<td>HIV RDT</td>
<td>SD BIOLINE HIV-1/2 3.0</td>
<td>03FK16; 03FK10; and 03FK17</td>
<td>RoW</td>
<td>Standard Diagnostics, Inc.</td>
<td>Giheung-gu, Republic of Korea</td>
<td>257T/kit; 307T/kit</td>
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</tbody>
</table>
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

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<tbody>
<tr>
<td>2013</td>
<td>HIV EIA</td>
<td>Genscreen™ ULTRA HIV Ag-Ab</td>
<td>72386; and 72388</td>
<td>CE-mark</td>
<td>Bio-Rad</td>
<td>Marnes La Coquette, France</td>
<td>96T/kit; 480T/kit</td>
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<td>2012</td>
<td>HIV RDT</td>
<td>*Uni-Gold™ HIV</td>
<td>1206502; 1206502N; 1206502E; 1206502-C; 1206502E-C; 1206502N-100; and 1206502-100</td>
<td>RoW</td>
<td>Trinity Biotech Manufacturing Ltd.</td>
<td>Bray, Ireland</td>
<td>20T/kit; 100T/kit</td>
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<td>2012</td>
<td>CD4 Technologies</td>
<td>Pima CD4 Test</td>
<td>260100025 and 260300003; 26030000100; and 260300003</td>
<td>CE-mark</td>
<td>Alere Technologies GmbH</td>
<td>Jena, Germany</td>
<td>25 cartridges/kit and instrument; 100 cartridges/kit and instrument</td>
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<tr>
<td>2012</td>
<td>CD4 Technologies</td>
<td>BD FACScan Instrument System with FACScan Control Kit and BD FACScan Reagent Kit (Absolute CD4+ Counts)</td>
<td>337858; 340166; 340167</td>
<td>CE-mark</td>
<td>Becton, Dickinson and Company, BD Biosciences</td>
<td>San Jose, CA, USA</td>
<td>337858: instrument system 340166: 25T/kit 340167: 50T/kit</td>
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<tr>
<td>2012</td>
<td>CD4 Technologies</td>
<td>BD FACScan Instrument System with FACScan Control Kit and BD FACScan CD4 Reagent Kit (Absolute and Percentage CD4+ Counts)</td>
<td>337858; 340166; 339010</td>
<td>CE-mark</td>
<td>Becton, Dickinson and Company, BD Biosciences</td>
<td>San Jose, CA, USA and Cayey, Puerto Rico</td>
<td>337858: instrument system 340166: 25T/kit 339010: 50T/kit</td>
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<td>2012</td>
<td>Virological Technologies</td>
<td>*COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 48)</td>
<td>05212294190; 03587797190; 03121453001; 03051335001 or 0580787500 and 07963084190; Optional: 05217503000; 28127387001</td>
<td>CE-mark</td>
<td>Roche Diagnostics GmbH</td>
<td>Mannheim, Germany</td>
<td>05212294190: 48T/kit 03587797190: 5.1 liters</td>
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<td>2012</td>
<td>Virological Technologies</td>
<td>*COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 96)</td>
<td>05212294190; 03587797190; 03279320001; 030513315001; 07347300001 or 05807875001 and 07963084190; Optional: 05217503000; 28127387001</td>
<td>CE-mark</td>
<td>Roche Molecular Systems Inc.</td>
<td>Branchburg, NJ, USA</td>
<td>05212294190: 48T/kit 03587797190: 5.1 liters</td>
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<td>2012</td>
<td>HIV RDT</td>
<td>HIV 1/2 STAT-PAK®</td>
<td>HIV101</td>
<td>RoW</td>
<td>Chembio Diagnostic Systems Inc.</td>
<td>Medford, NY, USA</td>
<td>20T/kit</td>
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<td>2011</td>
<td>Virological Technologies</td>
<td>NucliSENS EasyQ® HIV-1 v2.0 (Automated)</td>
<td>280140; 280130; 280131; 280132; 280133; 280134; 280506; 200309; and 285033</td>
<td>CE-mark</td>
<td>bioMérieux SA</td>
<td>Marcy l’Etoile, France</td>
<td>280130; 280131; 280132; 280133 and 280134: 4x1L 285033: 48 T/kit</td>
</tr>
<tr>
<td>Year prequalified</td>
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<tr>
<td>2011</td>
<td>Virological Technologies</td>
<td>NucliSENS EasyQ® HIV-1 v2.0 (Semi-Automated)</td>
<td>200305; 200293; 200292; 285056; 200309; and 285033</td>
<td>CE-mark</td>
<td>bioMérieux SA</td>
<td>Marcy L’Etoile, France</td>
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<td>Alere™ Determine HIV-1/2</td>
<td>7D2342; 7D2343; and 7D23435ET</td>
<td>RoW</td>
<td>Alere Medical Co. Ltd.</td>
<td>Matsudo-shi, Chiba-ken, Japan</td>
<td>20T/kit; 100T/kit; 100T/kit</td>
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<td>2011</td>
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<td>HIV 1/2 STAT-PAK® Dipstick</td>
<td>HIV303</td>
<td>RoW</td>
<td>Chembio Diagnostic Systems Inc.</td>
<td>Medford, NY, USA</td>
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<td>Virological Technologies</td>
<td>*Abbott RealTime HIV-1 (Manual)</td>
<td>2G31 (2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93</td>
<td>CE-mark</td>
<td>Abbott Molecular Inc.</td>
<td>Des Plaines, IL, USA</td>
<td>2G31-90: 96T/kit (4x24T); 2G31-80: 8 runs; 2G31-70: 4 calibration runs (1/6 months); 04J70-24: 96T/kit</td>
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<td>2011</td>
<td>Virological Technologies</td>
<td>*Abbott RealTime HIV-1 (m 2000sp)</td>
<td>2G31 (2G31-90 or 2G31-010, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; 04J71-93; and 9K14-02</td>
<td>CE-mark</td>
<td>Abbott Molecular Inc.</td>
<td>Des Plaines, IL, USA</td>
<td>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</td>
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<td>*Abbott RealTime e HIV-1 (m 24sp)</td>
<td>3N06-01, 2G31(2G31-90, 2G31-80, 2G31-70); 2G31-66; 1L68-09; 9K15-01; 04J70-24; and 04J71-93</td>
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<td>Des Plaines, IL, USA</td>
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<td>2010</td>
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<td>SD BIOLINE Malaria Ag P.f</td>
<td>0SFK30; 0SFK51; 0SFK52; 0SFK53</td>
<td>CE-mark</td>
<td>Standard Diagnostics, Inc.</td>
<td>Siheung-ku, Republic of Korea</td>
<td>257/kit; 25T/kit; 17/kit x 25 each; 17/kit x 25 each</td>
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</tbody>
</table>

*Public report was amended, please refer to public report for detailed amendments.*

**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/).**

End of document