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|--|---|
| <br>in process  | <br>stage complete |
| <p>Please note: these tables are updated regularly, while every attempt is made to provide current data, the most recent information might not be reflected. This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement.<br/>Last update: 1 July 2026</p> |   |











#### HIV Rapid Diagnostic Tests

| Product name                          | Product code(s)              | Manufacturer name                        | Dossier review  | Product performance evaluation            | Labelling review | Application number |
|---------------------------------------|------------------------------|--|---|---|------------------|--------------------|
| KHB HIV I/II Ab RAPID TEST            | R-429-50-C and R-429-50- C-1 | Shanghai Kehua Bio-engineering Co., Ltd. |  | Alternative laboratory evaluation pathway |                  | PQDx 13366-037-00  |
| KHB HIV I/II Ab RAPID TEST(SELF-TEST) | R-429-1- C-1                 | Shanghai Kehua Bio-engineering Co., Ltd. |  | Alternative laboratory evaluation pathway |                  | PQDx 13367-037-00  |




#### HBsAg Tests Rapid Diagnostic Tests

| Product name                             | Product code(s)                       | Manufacturer name           | Dossier review  | Product performance evaluation  | Labelling review | Application number |
|--|---------------------------------------|-----------------------------|---|---|------------------|--------------------|
| iStatis Hepatitis B Surface Antigen Test | 901149340007- 50<br>901149340008- 100 | bioLytical Laboratories Inc |  | Alternative laboratory evaluation pathway   |                  | PQDx 13489-002-00  |
| STANDARD Q HBsAg Test                    | 09HBS10D                              | SD Biosensor, Inc           |  |  |                  | PQDx 13342-117-00  |

#### Malaria Rapid Diagnostic Tests

| Product name   | Product code(s)   | Manufacturer name                           | Dossier review  | Product performance evaluation  | Labelling review  | Application number  |
|--|---|---|---|---|---|---------------------|
| Malaria P.f. Ag Rapid Test Cassette (Whole Blood)                    | GCMAL (pf)- 402a-1T, GCMAL (pf)-402a-25TX, and GCMAL (pf)-402a-25TD     | Zhejiang Orient Gene Biotech Co., LTD       |  |  |  | PQDx 12442-12940-00 |
| STANDARD Q hs-Malaria P.f./P.v Ag Test                               | 09MAL70D  | SD Biosensor, Inc.                          |  |  |  | PQDx 13200-117-00   |
| STANDARD Q hs-Malaria P.f Ag Test                                    | 09MAL60D  | SD Biosensor, Inc.                          |  |  |  | PQDx 13199-117-00   |
| First Response Malaria Ag. P. falciparum (HRP2/pLDH) Combo Card Test | PI25FRC05, PI25FRC10, PI25FRC25, PI25FRC30, PI25FRC10s, and PI25FRC25s. | Premier Medical Corporation Private Limited |  |   |   | PQDx 13764-010-00   |

#### Mycobacterium Tuberculosis complex and resistance to first and/or second line anti-TB drugs Tests

| Product name               | Product code(s)                                | Manufacturer name          | Dossier review  | Product performance evaluation            | Labelling review | Application number  |
|----------------------------|--|----------------------------|---|---|------------------|---------------------|
| Truenat MTB Plus           | 601130005, 601130020, 601130025, and 601130030 | Molbio Diagnostics Limited |  | Alternative laboratory evaluation pathway |                  | PQDx 13927-240-00   |
| GenoType MTBDRplus Ver 2.0 | 304A and 30496A                                | Hain Lifescience GmbH      |  |   |                  | PQDx 10294-09790-00 |
| Truenat MTB-RIF Dx         | 601210005, 601210020, 601210025, and 601210050 | Molbio Diagnostics Limited |  | Alternative laboratory evaluation pathway |                  | PQDx 14052-240-00   |

#### HPV Virological Technologies

| Product name        | Product code(s)                     | Manufacturer name   | Dossier review  | Product performance evaluation | Labelling review | Application number |
|---------------------|-------------------------------------|---------------------|---|--------------------------------|------------------|--------------------|
| LyoHarmony HPV Test | W-TD-0557-02-48 and W-TD-0557-02-96 | Shanghai ZJ Biotech |  |                                |                  | PQDx 14128-139-00  |

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