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|---|---|---|----------------------------------|--|
| <b>R</b><br>information requested<br>from manufacturer  | <br>in process | <br>stage complete | <b>F</b><br>follow-up amendments | <b>S</b><br>scheduled;<br>date confirmed |
| <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. Information may not yet be reflected here.</p> <p><b>Last update: 2 July 2024.</b><br/> <a href="https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment">https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment</a><br/> # The product was prequalified and a change request was submitted and accepted to add an intended use claim.</p> |   |   |                                  |  |

**Mycobacterium tuberculosis complex and resistance to first and/or second line anti-TB drugs Tests**

| Product name               | Product code(s)   | Manufacturer name                                   | Dossier review  | Quality Management System review  | Product performance evaluation            | Labelling review | Application number  |
|----------------------------|---|---|---|---|---|------------------|---------------------|
| BD MAX MDR-TB              | 443878  | Becton, Dickinson and Company, BD Biosciences (USA) | ◆   | ◆   | <b>R</b>                                  |                  | PQDx 10293-045-00   |
| Truenat MTB                | 601030005, 601030020, 601030025, 601030050, 601030100, and 601030200  | Molbio Diagnostics Private Limited                  |  |  |   |                  | PQDx 10311-240-00   |
| Truenat MTB Plus           | 601130020, 601130005, 601130025, 601130050, 6011301100, and 601130200 | Molbio Diagnostics Private Limited                  |  |  |   |                  | PQDx 10312-240-00   |
| Truenat MTB-RIF Dx         | 601210200, 601210005, 601210020, 601210100, 601210025, and 601210050  | Molbio Diagnostics Private Limited                  |  |  |   |                  | PQDx 10313-240-00   |
| cobas MTB-RIF/INH          | 09040617190, 09040625190, 09051953190, 08185476001                    | Roche Diagnostics GmbH                              | <b>R</b>  | <b>S</b>  | Alternative laboratory evaluation pathway |                  | PQDx 10304-118-00   |
| cobas MTB                  | 09040579190, 09040587190, 09051953190, 08185476001                    | Roche Diagnostics GmbH                              |  | <b>S</b>  | Alternative laboratory evaluation pathway |                  | PQDx 10306-118-00   |
| Loopamp MTBC Detection Kit | 972000, 970000, 971000  | Eiken Chemical Co., Ltd.                            | <b>R</b>  |   |   |                  | PQDx 10307-04545-00 |
| Xpert MTB/RIF Ultra        | GXMTB-ULTRA-HB-10 and GXMTB-ULTRA-HB-50                               | Cepheid AB  | ◆   |   | Alternative laboratory evaluation pathway |                  | PQDx 10295-070-00   |