

R information requested from manufacturer	 in process	 stage complete	F follow-up amendments	S scheduled; date confirmed
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. Last update: 2 December 2024. https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment # The product was prequalified and a change request was submitted and accepted to add an intended use claim.				

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)					PQDx 10293-045-00
Truenat MTB Plus	601130020, 601130005, 601130025, 601130050, 6011301100, and 601130200	Molbio Diagnostics Private Limited	R				PQDx 10312-240-00
Truenat MTB-RIF Dx	601210200, 601210005, 601210020, 601210100, 601210025, and 601210050	Molbio Diagnostics Private Limited	R				PQDx 10313-240-00
cobas MTB-RIF/INH	09040617190, 09040625190, 09051953190, 08185476001	Roche Diagnostics GmbH	R	S	Alternative laboratory evaluation pathway		PQDx 10304-118-00
cobas MTB	09040579190, 09040587190, 09051953190, 08185476001	Roche Diagnostics GmbH	R	S	Alternative laboratory evaluation pathway		PQDx 10306-118-00
Loopamp MTBC Detection Kit	972000, 970000, 971000	Eiken Chemical Co., Ltd.	R	S			PQDx 10307-04545-00
Xpert MTB/XDR	GXMTB/XDR-10	Cepheid AB			Alternative laboratory evaluation pathway		PQDx 10308-070-00