





 in process	 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. Last update: 19 June 2026</p>	











HIV Rapid Diagnostic Tests: progress of the active applications in the prequalification of IVDs assessment pipeline

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: Progress of the Prequalification of Diagnostics process by product

Product name	Product code(s)	Manufacturer name	Dossier review	Product performance evaluation	Labelling review	Application number
iStatis Hepatitis B Surface Antigen Test	901149340007- 50 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: progress of the active applications in the prequalification of IVDs assessment pipeline

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

Syphilis Rapid Diagnostic Tests: progress of the active applications in the prequalification of IVDs assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	Product performance evaluation	Labelling review	Application number
Determine Syphilis Advanced	7D3441, 7D3442, 7D3443SET, 7D3443, 7D3441SET, and 7D3442SET	Abbott Diagnostics Medical Co., Ltd.				PQDx 13641-013-00

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