in process	stage complete

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: 10 November 2026

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 Rapd 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 901149340008- 100	bioLytical Laboratories Inc		Alternative laboratory evaluation pathway		PQDx 13489-002-00

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
Malaria P.f./Pan Ag Rapid Test Cassette (Whole Blood)	GCMAL(pf/pan)-402a-1T, GCMAL(pf/pan)-402a-25TD, and GCMAL(pf/pan)-402a-25TX	Zhejiang Orient Gene Biotech Co., LTD				PQDx 12443-12940-00

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		*PE		PQDx 10294-09790-00
Truenat MTB-RIF Dx	601210005, 601210020, 601210025, and 601210050	Molbio Diagnostics Limited		Alternative laboratory evaluation pathway		PQDx 14052-240-00

*The product is under WHO's performance evaluation pipeline under the new PQ procedure. The pipeline is accessible at https://extranet.who.int/prequal/sites/default/files/document_files/26%2009%2028%20PE%20pipeline.pdf

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		Meijer's criteria were fulfilled in an independent evaluation.		PQDx 14128-139-00□

Glucose meters

Product name	Product code(s)	Manufacturer name	Dossier review	Product performance evaluation	Labelling review	Application number
VivaChek Ino Blood Glucose Monitoring System	VGM01-011, VGS01-011, VGL01-002, and VGC01-011	VivaChek Biotech (Hangzhou) Co., Ltd.		N/A		PQDx 12541-222-00□
STANDARD GlucoNavii GDH Blood Glucose Monitoring System	01GC30, 01GS30, 01GS30C, 01GS30D, 01GCS20, 01GCS21, 01GC32, and 01GM30	SD Biosensor, Inc.		N/A		PQDx 13799-117-00
SD CodeFree Blood Glucose Monitoring System, SD CodeFree Blood Glucose Meter, SD CodeFree Blood Glucose Test Strip, STANDARD Glucose Control Solution	01GC110, 01GC112, 01GM11, 01GS11, 01GC11C, 01GC11D, 01GCS10, 01GCS11, and 01GM11A	SD Biosensor, Inc.		N/A		PQDx 13801-117-00

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