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 July 2024

https://extranet.wo.nit/paweb/vitro-diagnostics/products-under-assessment

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	Quality Management System review	Product performance evaluation	Labelling review	Application number
HIV SELF TEST BY URINE – Human Immunodeficiency Virus (HIV) type-I urine antibody diagnostic kit (colloidal gold)		Beijing Wantai Biological Pharmacy Enterprise Co., Ltd		<b>♦</b>		PQDx 0544-005-00	
Asante HIV-1/2 Oral Self-Test	1503-20, 1503-50, 1503-100	Sedia Bioscences Corporation	R	S		PQDx 0662-265-00	
Asante HIV-1/2 Oral Fluid Test	1502-100	Sedia Bioscences Corporation	R	S		PQDx 0661-265-00	
Antenatal Care Panel	CPK-029	Abbott Diagnostics Medical Co., Ltd		<b>*</b>	No performance evaluation, as individual tests were evaluated previously	PQDx 0623-013-00	
First Response HIV 1-2.0 Card Test (Self-Test)	PI05FRCST	Premier Medical Corporation Private Limited		<b>*</b>			PQDx 0705-010-00