S information requested from manufacturer scheduled; follow-up amendments in process stage complete 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.

yet be relected nets.

Last update: Se March 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.

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	Quality Management System review	Product performance evaluation	Labelling review	Application number
STANDARD Q Syphilis Ab Test	09SYP10D, 09SYP10DM	SD Biosensor, Inc	R	*	•		PQDx 0477-117-00