





R information requested from manufacturer	 in process	 stage complete	F follow-up amendments	S scheduled; date confirmed
<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.Information may not yet be reflected here.</p> <p>Last update: 5 September 2025</p> <p>https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment</p> <p># The product was prequalified and a change request was submitted and accepted to add an intended use claim.</p>				

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
iStasis syphilis Ab Test	901150340003-50 and 901150340004-100	Biolytical Laboratories Inc			Alternative laboratory evaluation pathway		PQDx 12634-002-00
Determine Syphilis Advanced	7D3441, 7D3442, 7D3443SET, 7D3443, 7D3441SET, and 7D3442SET	Abbott Diagnostics Medical Co., Ltd.			Alternative laboratory evaluation pathway		PQDx 13641-013-00