

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: 25 November 2025 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.				

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
iStat [®] 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