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: 4 June 2021

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.

HIV Nucleic Acid Tests: progress of the active applications in the prequalification of IVDs assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	On-site inspection	Laboratory evaluation
cobas HIV-1 Quantitative nucleic acid test for use on the cobas 4800 Systems	06979599190; 06979572190; 06979513190; 06979521190; 05235863190; 05235871190; 06979556190; 06979530190; 06979548190	Roche Diagnostics GmbH	abridged assessment	◆	Alternative laboratory evaluation pathway
SAMBA II HIV-1 Qual Whole Blood Test	4500-12	Diagnostics for the Real World Ltd	abridged assessment	◆	Alternative laboratory evaluation pathway
SAMBA I HIV-1 Qual Whole Blood Test	4200-12	Diagnostics for the Real World Ltd	abridged assessment	◆	Alternative laboratory evaluation pathway
Accupower HIV-1 Quantitative RT-PCR	HIV-1111 (ROW ver.); HIV-1211 (CE version)	BIONEER Corporation	abridged assessment		🗁
SAMBA HIV-1 Semi-Q Test	4100-12	Diagnostics for the Real World Ltd	abridged assessment	◆	Alternative laboratory evaluation pathway
SAMBA II Semi-Q Whole blood test	4700-12, C19-0071, C19-0083	Diagnostics for the Real World Ltd	abridged assessment	◆	Alternative laboratory evaluation pathway
cobas HIV-1/HIV-2 Qualitative nucleic acid test for use on the cobas 6800/8800	7862113190	Roche Molecular Systems, Inc.	abridged assessment		Alternative laboratory evaluation pathway