





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: 28 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.</p>				

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	Quality Management System review	Product performance evaluation	Labelling review	Application number
Accupower HIV-1 Quantitative RT-PCR	HIV-1111 (ROW ver.); HIV-1211 (CE version)	BIONEER Corporation	abridged assessment	◆	◆		PQDx 0454-140-00
SAMBA II Semi-Q Whole blood test	4700-12, C19-0071, C19-0083	Diagnostics for the Real World Ltd	abridged assessment	S	Alternative laboratory evaluation pathway		PQDx 0479-072-00
Alinity m HIV-1	08N45-090	Abbott Molecular Inc.		◆	◆	◆	PQDx 0640-027-00
Xpert HIV-1 Viral Load XC	GXHIV-VL-XC-CE-10	Cepheid AB		◆	Alternative laboratory evaluation pathway	◆	PQDx 0691-070-00