





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. 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>				

HPV 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
cobas 4800 HPV	05235880190, 05235898190, 05235855190, 05235782190	Roche Molecular Systems, Inc	◆		Alternative laboratory evaluation pathway		PQDx 0466-046-00
Aptima HPV Assay	302929, 303093, 302554	Hologic, Inc.	R	◆	Alternative laboratory evaluation pathway		PQDx 0633-078-00
Aptima HPV 16 18/45 Genotype Assay	303236, 303235	Hologic, Inc.	R	◆	Alternative laboratory evaluation pathway		PQDx 0634-078-00
Alinity m HR HPV	09N15-090, 09N15-080	Abbott Molecular Inc		◆	Alternative laboratory evaluation pathway		PQDx 09308-027-00