










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: 27 June 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>				

HPV 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
Aptima HPV Assay	302929, 303093, 302554	Hologic, Inc.			Alternative laboratory evaluation pathway	R	PQDx 0633-078-00
Aptima HPV 16 18/45 Genotype Assay	303236, 303235	Hologic, Inc.			Alternative laboratory evaluation pathway	R	PQDx 0634-078-00
BD Onclarity HPV Assay for the BD COR System	443982	Becton, Dickinson and Company, BD Biosciences (USA)				R	PQDx 12411-045-00
BD Onclarity HPV Assay for the BD Viper LT System	442946	Becton, Dickinson and Company, BD Biosciences (USA)				R	PQDx 12315-045-00
ScreenFire HPV RS	M5FHPV-96	Atila Biosystems	R				PQDx 12643-13346-00
Human Papillomavirus (HPV) Nucleic Acid Detection Kit (Hybrid Capture-CLIA)	DH3-48, DH3-72, DH3-96 and DH3-192	Hangzhou Dalton BioSciences, Ltd					PQDx 11588-10152-00