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| <b>R</b><br>information requested from<br>manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <br>in process | <br>stage complete | <b>F</b><br>follow-up amendments | <b>S</b><br>scheduled;<br>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><b>Last update: 20 October 2025</b></p> <p><a href="https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment">https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment</a></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                                                                      | Product performance evaluation | Labelling review                                                                    | Application number  |
|-----------------------------------------------------------------------------|------------------------------------|----------------------------------|-------------------------------------------------------------------------------------|--------------------------------|-------------------------------------------------------------------------------------|---------------------|
| Aptima HPV Assay                                                            | 302929, 303093, 302554             | Hologic, Inc.                    |  | Waived                         |  | PQDx 0633-078-00    |
| Aptima HPV 16 18/45 Genotype Assay                                          | 303236, 303235                     | Hologic, Inc.                    |  | Waived                         |  | PQDx 0634-078-00    |
| ScreenFire HPV RS                                                           | M5FHPV-96                          | Atila Biosystems                 |  |                                |                                                                                     | 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 | <b>R</b>                                                                            |                                |                                                                                     | PQDx 11588-10152-00 |