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|---|---|---|----------------------------------|--|
| <b>R</b><br>information requested from 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: 5 September 2025</b><br/> <a href="https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment">https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment</a><br/> # 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 | ◆                | PQDx 0633-078-00    |
| Aptima HPV 16/18/45 Genotype Assay  | 303236, 303235                     | Hologic, Inc.                                       |    | ◆                                | Alternative laboratory evaluation pathway | ◆                | PQDx 0634-078-00    |
| BD Onclarity HPV Assay for the BD COR System                                | 443982                             | Becton, Dickinson and Company, BD Biosciences (USA) | ◆   |                                  |   | ◆                | PQDx 12411-045-00   |
| BD Onclarity HPV Assay for the BD Viper LT System                           | 442946                             | Becton, Dickinson and Company, BD Biosciences (USA) | ◆   |                                  |   | ◆                | PQDx 12315-045-00   |
| ScreenFire HPV RS   | M5FHPV-96                          | Atila Biosystems                                    | <b>R</b>  |                                  |   |                  | 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 |