

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                 |                                                                                                     |                                  |                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------------|
| <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: 4 June 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> |                                                                                                 |                                                                                                     |                                  |                                          |

**HIV/Syphilis/HBsAg Combo Rapid Diagnostic 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 |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------|
| MERISCREEN HIV + Syphilis Antibody Test | <div><input type="checkbox"/></div> RPDHIS-01, RPDHIS-02, RPDHIS-03, RPDHIS-04, RPDHIS-05, RPDHIS-06, RPDHIS-07, RPDHIS-08, RPDHIS-09, RPDHIS-10 | Meril Diagnostics Pvt.Ltd      |  |  |  |  | PQDx 12387-074-00  |
| Determine Antenatal Care Panel          | CPK-038                                                                                                                                          | Abbott Diagnostics Medical Co. |  |                                                                                     | Waived.                                                                             | <b>R</b>                                                                            | PQDx 13226-013-00  |