1. **PREQUALIFIED IVDs**

The following IVDs have been prequalified in Q3 2019:

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product code(s)</th>
<th>Manufacturer</th>
<th>Date of Prequalification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mylan HIV Self Test</strong></td>
<td>ARST001-03</td>
<td>Atomo Diagnostics Pty Ltd</td>
<td>3 July 2019</td>
</tr>
<tr>
<td><strong>ARCHITECT HCV Ag assay</strong></td>
<td>6L47-29, 6L47-11, 6L47-02, 8C89-01</td>
<td>Denka Seiken Co.</td>
<td>31 July 2019</td>
</tr>
<tr>
<td><strong>Determine HBsAg 2</strong></td>
<td>7D2942, 7D2943, 7D2943 SET</td>
<td>Alere Medical Co. Ltd</td>
<td>2 September 2019</td>
</tr>
<tr>
<td><strong>First Response HIV 1-2.O Card test (Version 2.0)</strong></td>
<td>PI05FRC25, PI05FRC30, PI05FRC50, PI05FRC60, PI05FRC100</td>
<td>Premier Medical Corporation Private Limited</td>
<td>16 September 2019</td>
</tr>
</tbody>
</table>

For a complete list of prequalified products, click [here](#).

For a list of products undergoing prequalification assessment, [visit this page](#).

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2. **ADDITIONAL GUIDANCE AVAILABLE AND UNDER DEVELOPMENT**
Continuing its efforts to support prequalification applicants and increase transparency WHO has developed or is developing the following documents under its Technical Specifications (TSS) and Technical Guidance Series (TGS).

**New guidance published include:**

- TSS 7 - [Rapid diagnostic tests to detect hepatitis C antibody or antigen](#)
- TSS 8 - [Imunoassays to detect hepatitis C antibody and/or antigen](#)

**Public comments on the below guidance are expected by 15 October 2019:**

- TSS-10 - In vitro diagnostic (IVDs) medical devices used for the qualitative and quantitative detection of Hepatitis C RNA
- TSS-11 - In vitro diagnostic (IVDs) medical devices used for the quantitative detection of HIV-1 nucleic acid
- TSS-12 - In vitro diagnostic (IVD) medical devices used for the qualitative detection of HIV-1 and HIV-2 nucleic acid

The development of three new TSS documents is ongoing, with public consultations for each of them expected to be launched in Q4 2019:

- TSS-13 - Rapid diagnostic tests to detect hepatitis B surface antigen (HBsAg)
- TSS-14 - Immunoassays to detect hepatitis B surface antigen (HBsAg)
- TSS-15 - In vitro diagnostic (IVDs) medical devices used for the quantitative detection of Hepatitis B nucleic acid

In addition, the development of a TSS for hemoglobin has been undertaken and will undergo public consultation in 2020.

### 3. CALL FOR APPLICATIONS: Cholera RDTs, Syphilis RDTs, HPV assays and G6PD assays


Applicants can access the respective prequalification technical specifications for [Cholera RDTs, Syphilis RDTs, HPV assays](#) and [G6PD assays](#) on the WHO prequalification website. Manufacturers are welcome to contact the Prequalification Team for further guidance on the assessment process and/or requirements for these products at [diagnostics@who.int](mailto:diagnostics@who.int).
4. COLLABORATIVE PROCEDURE FOR IVDs: PILOT PROJECT UPDATE

In Q2 2019 WHO launched a pilot project which aims to expand the existing collaborative registration procedure (CRP) to in vitro diagnostics. The CRP is well established in the area of medicines and has the potential to contribute to an improved access to priority in vitro diagnostics (IVDs) of assured quality, safety, and performance.

A one-year pilot project aiming at introducing the CRP for IVDs has started in Q3 2019. Five countries have been selected to participate in the pilot project: Cameroon, Cote d’Ivoire, Ethiopia, Nigeria, and the United Republic of Tanzania. The product selected for the CRP-IVD pilot is the m-PIMA HIV-1/2 VL test with product code 27015-W50 using m-PIMA Analyser (product code 27030R001), manufactured by Alere Technologies GmbH (a wholly owned subsidiary of Abbott Laboratories), rest of the world regulatory version. This product was prequalified on 8 April 2019, the respective public report can be found here.

It is expected that, as part of the project, at least 3 of the 5 pilot countries will register the product undergoing the CRP, and that the methodologies drafted for the implementation of this procedure will be finalized before the CRP for IVDs is expanded to other countries and regions. The pilot project will also assist Member States in unpacking the current national registration procedures, understanding the existing burden and duplication and optimizing opportunities for reliance on prequalification listing. WHO will assess the information gathered throughout the pilot project to assist Member States in optimizing regulatory processes and procedure to better support timely access to quality assured IVDs.

5. GLOBAL DIAGNOSTICS WORKING GROUP (GDWG): UPDATE ON ON-GOING PROJECTS

The GDWG was formed to provide a forum for contributing organizations to share information on quality assurance (QA) of HIV-related in vitro diagnostics (IVDs). The objectives of the GDWG are:

- To strengthen communication, collaboration & coordination among GDWG members for the optimal selection and use of quality-assured HIV-related IVDs.
- To effectively respond in a timely and coordinated manner to urgent quality-related issues that may arise in the context of HIV-related IVDs, such as quality or post-market surveillance issues.
- To provide aligned messages to global, regional, and country level users on QA for product selection and testing implementation, including post-market surveillance.
- To provide aligned messages to manufacturers regarding QA requirements for IVDs.
- To advocate for diagnostics that are appropriate and affordable for use in resource-limited settings.

The following institutions are currently GDWG members: Centers for Disease Control and Prevention (CDC), Clinton Health Access Initiative (CHAI), The Global Fund for HIV, TB, and Malaria (Global Fund), Médecins Sans Frontières (MSF), US Office of the Global AIDS Coordinator (OGAC), United Nations Development Programme (UNDP), United Nations International Children’s Emergency Fund
(UNICEF), UNITAID, US Agency for International Development (USAID) and the World Health Organization (WHO).

In addition to their regular work GDWG members are heavily invested in the following projects:

- The **Rome Action Plan** (also known as “Vatican initiative”);
- The collaborative registration procedure (CRP) for IVDs;
- Roles and responsibilities in HIV IVDs assessments;
- Error rates for post-market surveillance of IVDs; and
- Model certificate of analysis for IVDs.


The GDWG is developing an approach to HIV IVDs assessments. The objective of this initiative is to ensure that:

- action among stakeholders is coordinated and supports timely access to quality assured HIV IVDs;
- countries focus on generating need-based evidence, considering available resources and addressing priority needs;
- each actor at country level actively looks for and utilizes existing relevant evidence to support registration, HTA and HTM;
- access to innovative products is enabled; and
- synergistic approaches boost access and support universal health coverage.

The above approach will build on agreed upon definitions of terms, clear roles and responsibilities, spanning from manufacturers, national regulatory authorities to HTA/HTM/product selection, under a synergistic approach aiming at:

- removing barriers;
- redirecting and streamlining product assessment efforts;
- using resources efficiently;
- using existing evidence and assessing characteristics lacking evidence;
- adopting a needs-based approach;
- facilitating and supporting the uptake of quality assured, cost-effective innovative IVDs;
- leveraging regional and international collaboration mechanisms;
- adapting approaches to reflect quality-assurance levels; and
- leveraging post-market surveillance as a risk mitigation measure to complement pre-market and HTA activities.

These same efforts will be reinforced through a WHO-UNITAID partnership in Optimizing UNITAID’s investments to overcome regulatory and product selection barriers for IVDs and other medical devices. The partnership will build on existing projects such as WHO prequalification and its collaborative registration procedure, Point-of-Care HIV diagnostics project, STAR and ATLAS projects.
for self-testing and the Cervical Cancer project, and will aim at resolving bottlenecks, generating best practice and working in close collaboration with key partners.

7. REGISTRATION OPEN FOR THE UNICEF, UNFPA & WHO JOINT MEETING WITH MANUFACTURERS AND SUPPLIERS

The meeting will take place on 2-5 December 2019 at UN City, Marmorvej 51, 2100 Copenhagen, Denmark. Registration is now open.

You can find more information about the meeting here, including the programme description.

To request a face-to-face meeting with our team please contact Charles Chiku at chikuc@who.int

To subscribe or unsubscribe to the Prequalification of In Vitro Diagnostics mailing list, send an email to diagnostics@who.int with subscribe or unsubscribe in the subject.

http://www.who.int/diagnostics_laboratory/evaluations/en/