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1. **PREQUALIFIED IVDs**

The following IVDs have been prequalified in Q2 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>m-PIMA HIV-1/2 VL</strong></td>
<td>27015-W50</td>
<td>Alere Technologies GmbH</td>
<td>8 April 2019</td>
</tr>
<tr>
<td><strong>Alere Malaria Ag P.f</strong></td>
<td>05FK140, 05FK141, 05FK142, 05FK143</td>
<td>Standard Diagnostics, Inc.</td>
<td>12 April 2019</td>
</tr>
<tr>
<td><strong>AdvDx Malaria Pf Rapid Malaria Ag Detection Test</strong></td>
<td>00-DKM-RK-MALADX-004-025</td>
<td>Advy Chemical Pvt Ltd</td>
<td>16 May 2019</td>
</tr>
<tr>
<td><strong>Rapid Anti-HCV Test</strong></td>
<td>ITPWO1152-TC40, ITPWO1152-TC25, ITPWO1153-TC40</td>
<td>InTec PRODUCTS, INC</td>
<td>17 May 2019</td>
</tr>
<tr>
<td><strong>ONE STEP Anti-HIV (1&amp;2) Test</strong></td>
<td>ITPWO2152-TC40, ITPWO2152-TC25, ITPWO2153-TC40</td>
<td>InTec PRODUCTS, INC</td>
<td>17 May 2019</td>
</tr>
<tr>
<td><strong>First Response HIV1+2/Syphilis Combo Card Test</strong></td>
<td>I20FRC25, I20FRC30, I20FRC50, I20FRC60, I20FRC100</td>
<td>Premier Medical Corporation Private Limited</td>
<td>24 June 2019</td>
</tr>
</tbody>
</table>
2. UPDATE ON THE ALTERNATIVE PERFORMANCE EVALUATION PATHWAY UPTAKE

To address challenges faced with past performance evaluations, including delays in timelines and availability of evaluating laboratories, the alternative performance evaluation pathway has been gradually introduced since 2016. Manufacturers are currently invited to choose between two options for the performance evaluation of their product, and to indicate their choice in each product pre-submission form. Under option 1, the performance evaluation is coordinated by WHO. Under option 2, the performance evaluation is commissioned and paid for by the manufacturer. In contrast to the old pathway, the performance evaluations can be scheduled as soon as the product is prioritized by WHO as meeting WHO eligibility criteria, to avoid delays and contain overall assessment timelines.

In both cases, the main aim of the prequalification performance evaluation remains the submission of independently generated data required for the WHO prequalification assessment, in addition to the manufacturer’s validation data submitted in the product dossier. All evaluations are performed according to standardized protocols for WHO prequalification assessment, which can be found here, and carried out at a Prequalification Evaluation Laboratory (PEL) listed by WHO. Data and analyses are verified by WHO. There are currently 12 PELs listed under the WHO Prequalification alternative performance evaluation mechanism, most of which have agreed to perform evaluations under both options (the list can be found here).

The uptake of option 2 manufacturer commissioned performance evaluations has been increasing, with 2 out of 8 evaluations submitted in 2017, 3 out of 13 products submitted in 2018, and 6 out of 7 products submitted since the beginning of 2019 using this option for performance evaluation. WHO has been monitoring the impact of this mechanism on prequalification assessment timelines as part of its performance management.

3. COMING SOON: NEW PRODUCT DOSSIER STRUCTURE

The WHO Prequalification Team, Diagnostics Assessment Group accepts product dossier submissions for in vitro diagnostics (IVDs) that use the Global Harmonization Task Force (GHTF) summary technical document (STeD) format. The STeD format of product dossier is intended to allow manufacturers of IVDs to summarise the information from their technical file – a collection of all technical information gathered during the design, development and validation of an IVD – in a way that demonstrates compliance with the relevant Essential Principles of quality, safety and performance.

The GHTF’s successor, the International Medical Device Regulators Forum (IMDRF), has developed a new format for IVD product dossiers. The IMDRF Table of Contents (ToC) format is intended to be a globally harmonized reporting format. It features consistent numbering of detailed report chapters with guidance on how to populate each section. This format allows the risk class of devices to be addressed, and for differences between globally-harmonized requirements and local requirements to be managed.

The WHO Prequalification Team, Diagnostics Assessment Group will begin implementing the ToC format for both incoming product dossiers and its dossier review reports in 2020. Implementation will begin with a pilot programme that will consist of the launch of new instructions for compilation of a product dossier and new reporting templates. Following the launch of the ToC format a transition period will allow applicants to submit product dossiers in either ToC or STeD format, after which the ToC format will be adopted as the standard format in 2021.
4. ADDITIONAL GUIDANCE AVAILABLE

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).

The public consultation for the below documents has closed. Comments are undergoing review and the final versions of documents are expected to be published in Q3 2019:

- TSS 7 - Rapid diagnostic tests to detect hepatitis C antibody or antigen
- TSS 8 - Immunoassays to detect hepatitis C antibody and/or antigen
- TSS 9 - Immunoassays to detect HIV antibody and/or antigen
- TGS 8 - Quality control for in vitro diagnostic medical devices for WHO prequalification

The development of three new TSS documents is ongoing, with public consultations for each expected to begin in Q3 2019:

- TSS-10 - IVDs used for the qualitative and quantitative detection of hepatitis C ribonucleic acid (RNA) by nucleic acid testing
- TSS-11 - IVDs used for the quantitative detection of HIV-1 RNA by nucleic acid testing
- TSS-12 - IVDs used for the qualitative detection of HIV-1 and HIV-2 by nucleic acid testing

Changes to a WHO prequalified in vitro diagnostic guidance document under review
Document PQDx_121 v2 "Reportable Changes to a WHO Prequalified In Vitro Diagnostic Medical Device" is undergoing revision. A new version of the guidance document is expected to be published by the end of 2019.

Changes to a WHO prequalified male circumcision device guidance document
Documents PQMC_121 v1 "Reportable Changes to a WHO Prequalified Male Circumcision Device" and PQMC_119 v1 “Change Reporting Form for a WHO Prequalified Male Circumcision Device” have been finalised and are available at https://www.who.int/diagnostics_laboratory/male_circumcision/change/en/

5. NEW ABRIDGED ASSESSMENT PROCEDURE UNDER DEVELOPMENT

The abridged prequalification assessment procedure for IVDs has been in place since 2014. The aim of abridged prequalification assessment is to avoid duplication of effort and to reduce the time taken to prequalify a product by focusing on aspects of WHO prequalification assessment providing added value.

WHO initiated the revision of the current abridged assessment procedure to address three items: changes in regulations in jurisdictions recognised as performing stringent reviews; exploring opportunities for the addition of other jurisdictions to the list of authorities recognised under the abridged assessment; and to reflect the evolving international harmonization initiatives under the International Medical Device Regulators Forum, including the Medical Device Single Audit Programme. It is expected that the new procedure will undergo public consultation in Q4 2019 to be fully implemented in 2020.

6. CALL FOR APPLICATIONS: Cholera RDTs, Syphilis RDTs, HPV assays and G6PD assays
With reference to the [Global Guidance on Criteria and Processes for Validation: Elimination of mother-to-child transmission of HIV and Syphilis (EMTCT)](updated December 2017), [WHO guidelines on syphilis screening and treatment for pregnant women], [Ending Cholera – A Global Roadmap to 2030], [Guidelines for screening and treatment of precancerous lesions for cervical cancer prevention] and the [Guide to G6PD deficiency rapid diagnostic testing to support P. vivax radical cure], WHO encourages manufacturers of Cholera and Syphilis RDTs, and HPV and G6PD assays to apply for prequalification assessments.

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

### 7. COLLABORATIVE PROCEDURE FOR IVDs

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.

In the WHO African region many national regulatory authorities (NRAs) face challenges related to weak governance, human, technical, logistic and financial capacities, in addition to fragmented and non-exhaustive regulatory texts. One third of countries in this region have an autonomous or semi-autonomous NRA. This situation leads to long turn-around times for the registration of IVDs and complex processes, contributing to delays that compromise the provision of health care. The CRP aims to accelerate registration decisions for WHO-prequalified products in participating countries through the sharing of confidential assessment reports with regulatory bodies, at the request of manufacturers.

A one-year pilot project will be implemented with selected countries for the CRP for IVDs. The pilot collaborative registration procedure for accelerated registration of WHO Prequalified in vitro diagnostics workshop was held in Dar Es Salaam, United Republic of Tanzania from 24 to 25 April 2019, and was attended by 12 representatives from NRAs participating in the WHO CRP for IVDs in the African region, WHO Regional Office, Tanzania WHO Country Office, and WHO Prequalification (PQT) and Regulatory Systems Strengthening (RSS) Teams. Five countries already registering IVDs have been selected to participate in the pilot project. They include Cameroon, Cote d’Ivoire, Ethiopia, Nigeria, and the United Republic of Tanzania. The workshop was facilitated by the WHO Prequalification Team and the Regulatory Systems Strengthening Team from headquarters (WHO HQ, Geneva) and the African region. It is expected that, as part of the project, at least 3 of the 5 pilot countries will register a 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.
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/