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RECENTLY PREQUALIFIED IVDs

We are very pleased to announce the prequalification of the following products:

<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>One Step Test for Malaria Pf /Pv Ag MERISCREEN Malaria Pf/Pv Ag</td>
<td>MFLRPD-02</td>
<td>Meril Diagnostics Pvt. Ltd.</td>
<td>9 November 2018</td>
</tr>
<tr>
<td>One Step HIV 1/2 Whole Blood/Serum/Plasma Test</td>
<td>W006-C4P2 W006-C4P2-F</td>
<td>Guangzhou Wondfo Biotech Co., Ltd</td>
<td>29 November 2018</td>
</tr>
<tr>
<td>INSTI® HIV Self Test</td>
<td>90 - 1071</td>
<td>bioLytical Laboratories Inc.</td>
<td>30 November 2018</td>
</tr>
<tr>
<td>SD Bioline Malaria Ag Pf/Pf/Pv</td>
<td>05FK120 05FK123</td>
<td>Standard Diagnostics, Inc.</td>
<td>04 December 2018</td>
</tr>
<tr>
<td>First Response Malaria Antigen P. falciparum (HRP2) Card Test</td>
<td>PI13FRC25 PI13FRC30 PI13FRC25s PI13FRC10s</td>
<td>Premier Medical Corporation Private Limited</td>
<td>04 December 2018</td>
</tr>
<tr>
<td>First Response Malaria Ag pLDH/HRP2 Combo Card Test</td>
<td>PI16FRC25 PI16FRC30 PI16FRC10s</td>
<td>Premier Medical Corporation Private Limited</td>
<td>04 December 2018</td>
</tr>
</tbody>
</table>
For a complete list of prequalified products, click here.

For a list of products undergoing prequalification assessment, visit this page.

ELIGIBILITY FOR PREQUALIFICATION OF IVDs

A consultation has been organized to gather input from key stakeholders in order to determine the types of in vitro diagnostics for which prequalification is most needed and for which it will have the greatest benefit. The consultation should allow to map the most needed quality assured IVDs and should embrace the following concepts:

- burden of disease;
- health interventions associated with particular IVDs;
- existing WHO guidelines;
- EDL listing (if available prior to the consultation);
- available/expected donor funding.

Based on received feedback a priority level for inclusion on the prequalification scope will be assigned for each type of IVD based on the above criteria. The priority level will be used to determine timelines for inclusion in the prequalification of IVDs scope.

To provide your input click here.

IMPLEMENTATION OF TECHNICAL SPECIFICATION REQUIREMENTS

Over the past few years, WHO has been developing technical specifications for IVDs eligible to undergo a WHO prequalification assessment. These documents aim at guiding manufacturers in gathering the evidence necessary to fulfil WHO requirements to demonstrate performance of their IVDs. Since the publication of the first TSS document in 2016, manufacturers have been implementing them in their submissions and within their testing plans ahead of submission. TSS documents have been greatly appreciated by
manufacturers and WHO assessors who welcome the increased transparency around WHO requirements and ease with which decisions are taken during the review.

While the assessment of products having been prequalified before the publication of the TSS documents followed a comprehensive and rigorous process, certain TSS requirements were not necessarily considered at the time of their review. In early 2019, WHO will be reaching to manufacturers to inform them that for those IVDs where technical specifications are in effect, compliance will be required as follows:

- For prequalified IVD products, manufacturers will be given **3 years** from their notification to ensure compliance.
- New submissions, for which a TSS has been published for more than **3 months**, will be assessed against the new requirements.
- New submissions for which a TSS has been published for less than **3 months**, will be assessed against ‘old’ requirements and if prequalified, will be given **3 years** from the date of prequalification to ensure compliance with new TSS requirements.

**What are the next steps for manufacturers for prequalified IVDs?** Manufacturers are expected to conduct a gap analysis to understand what aspects of their technical documentation do not comply with the applicable TSS. They will be required to develop a corrective action plan and conduct additional studies to demonstrate compliance with TSS.

**How will WHO monitor compliance for prequalified products?** Manufacturers will be required to inform WHO that a gap analysis has been conducted and that certain validation studies have been carried out to ensure compliance. The manufacturer’s evidence will be assessed and a decision reached regarding compliance to the TSS. The implementation will be reviewed as an additional documentation review and/or during the routine re-inspection. The lack of evidence of implementation may result in the termination of the application or delisting of the product.

More information will be provided in the communication to manufacturers. For any queries, contact diagnostics@who.int.

**CALL FOR APPLICATIONS: HPV IVDs and syphilis RDTs**

WHO is actively seeking applications for IVDs intended as a screening tool for the detection of high risk HPV.

Current **WHO recommendations** advocate for a “screen and treat” approach using tools such as HPV tests. There are currently only two prequalified HPV screening assays. Prequalification of additional products would greatly contribute to the ongoing efforts towards elimination of cervical cancer.

Manufacturers are highly encouraged to submit an application. An overview of the prequalification process can be found [here](#). The submission form can be found [here](#).
Read all about the WHO Director General’s call for action towards the elimination of cervical cancer.

In addition, WHO would like to remind manufacturers that as Q1 2019, WHO will be accepting applications for syphilis rapid diagnostic tests (RDTs). Manufacturers are encouraged to review the Technical Specifications document that will be published for syphilis RDTs before submitting an application. A separate communication will be sent to all stakeholders upon final publication of the TSS.

JOINT UNFPA–UNICEF WHO MEETING WITH MANUFACTURERS AND SUPPLIERS OF IN VITRO DIAGNOSTIC PRODUCTS

The annual joint UNFPA–Unicef-WHO meeting took place at UN City, Copenhagen, Denmark from 24 to 27 September 2018 and was attended by around 400 participants from all over the world, including manufacturers, procurers and other stakeholders. This year’s theme was “Where the World is Going and What We Should do Next”: providing manufacturer’s with an overview of current procurement practices and challenges, updates on diagnostic and treatment guidelines as well as discussions on possible actions that could help tackle tomorrow’s health challenges. IVDs were discussed in several plenary and breakout sessions. Of note was the HPV session in which participants were able to hear about upcoming changes to screening and treatment guidelines for HPV and the challenges in implementing HPV screening and treatment programmes in lower income settings. In addition, a plenary session discussed the recent development and publication of the first Model List of Essential In Vitro Diagnostics.

As in previous years, the Prequalification of In Vitro Diagnostics group held a series of one-to-one meetings with manufacturers that are either undergoing a prequalification assessment for one of their products or are thinking of submitting an application. These meetings are a great opportunity for manufacturers to address any issues and queries in the presence of the entire team. In addition, a session was held to provide an update on the PQ processes, the new alternative performance evaluation mechanism and the new technical guidance published.

ASLM 2018 CONFERENCE ABUJA, NIGERIA

WHO was present at the ASLM 2018 Conference which took place from 9 to 13 December 2018 with the following seminars:

*WHO Prequalification of in vitro diagnostics: laboratories’ role under the alternative performance evaluation.* (If you would like to access any of the presentations, please send an email to diagnostics@who.int)
Post-marketing surveillance for HIV self-testing.

Introduction to WHO’s Essential Diagnostics List (EDL).

The book of abstracts for the conference can be accessed and downloaded here.

INTRODUCTION OF A NEW IT SOLUTION
WHO has been working on a new IT solution which will contribute to an enhanced traceability and transparency of prequalification applications. This platform will introduce a fully electronic submission for Prequalification of In Vitro Diagnostics and Male Circumcision Devices, and Emergency Use Assessment and Listing submissions for IVDs. Manufacturers will be able to upload documents directly into the system and access information on their applications in real time. It is expected that the new IT solution will be launched in Q2 2019.

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/