Scope of WHO prequalification of in vitro diagnostics expanded to include IVDs for the detection of Vibrio cholera

Cholera continues to be a major public health problem with an estimated 1.3 to 4.0 million cases resulting in 21 000 to 143 000 deaths annually worldwide, principally in Africa, Southern Asia and the Caribbean. Cholera systematically affects countries with limited resources where access to clean water and sanitation systems remains problematic and surveillance systems are weak, hampering a quick response.

Accurate cholera diagnosis is potentially of high public health impact. The Secretariat of the Global Task Force on Cholera Control (GTFCC) at WHO, in agreement with key partners, has therefore recommended that WHO IVD prequalification scope be extended to include IVDs for the detection of Vibrio cholerae. Rapid diagnostics tests (RDTs) for the detection of Vibrio cholera that serve the needs of countries with limited resources will become eligible for prequalification assessment.

Assays evaluated for prequalification undergo a standardized assessment of safety, quality and performance. For cholera IVDs RDTs this will consist of a full prequalification assessment, including a product dossier review, a performance evaluation and manufacturing site inspection. Click here for more information about the process.

In order to support this work, WHO will be developing, through a consultative process, Technical specifications for cholera RDTs, as part of its Technical Specifications Series (TSS). This document will inform manufacturers about WHO requirements regarding validation and verification of cholera RDTs submitted for prequalification assessment. Additionally, a draft performance evaluation protocol will be developed. Both documents will be presented at an expert consultation to be held at the end in Q4 2017. The TSS document is expected to be available for public comment in Q4 2017 for a period of one month before its finalization and publication.

In addition, the GTFCC Secretariat has set up an expert group to support the development of a Target Product Profile (TPP) for Cholera RDTs. The document specifies RDT characteristics that will guide manufacturers in the development and production of affordable, quality RDTs enabling early detection of cholera outbreaks. The TPP for cholera RDTs has been finalized and will be published shortly on the GTFCC website.

Applications for prequalification assessment will be accepted as of 1 January 2018.

---

1 [Updated global burden of cholera in endemic countries.](https://doi.org/10.1371/journal.pntd.0003832).

Call for dual HIV/syphilis rapid diagnostic test applications

Since prequalification of the first RDT for detecting anti-HIV and anti-Treponema pallidum (dual HIV/syphilis RDT) in 2015, countries have started to implement dual testing in routine antenatal testing programmes and in other settings. Screening all pregnant women for HIV and syphilis is recommended by WHO and in nearly all countries of the world. But although the testing of pregnant women for HIV is relatively well-resourced, syphilis infected women often go undiagnosed and untreated. Additional populations such as men who have sex with men, transgender people, injecting drug users and sex workers would also benefit from improved HIV and syphilis screening coverage. This will, in part, depend upon a healthy market for this type of IVD, which will call for a broader range of products from which procurers and end users can select. WHO is therefore calling for additional manufacturers of dual HIV/syphilis RDTs to submit their products for prequalification assessment.

Manufacturers wishing to apply should complete a pre-submission form and send it to diagnostics@who.int. For more information on the recommended use of dual HIV/syphilis RDTs within a testing strategy please click on this link.

Additional guidance

The following drafts in the Technical Guidance Series are now available:

- **TGS 5 Designing Instructions for use for in vitro diagnostic medical devices**: This document is intended to provide guidance to manufacturers on best practice when designing the instructions for use.

- **TGS 6 Panels for quality assurance and quality control of in vitro diagnostic medical devices**: The purpose of this document is to provide IVD manufacturers with guidance on possible approaches in preparing validation panels for quality assurance (QA) and quality control (QC).

We invite you to provide comments by 31 July 2017 to diagnostics@who.int using the tables provided at the following links:

- **TGS 5 Designing Instructions for use for in vitro diagnostic medical devices**
- **TGS 6 Panels for quality assurance and quality control of in vitro diagnostic medical devices**

We would also like to bring to your attention the publication of the third document in the Technical Specifications Series (TSS): TSS-3 Malaria rapid diagnostic tests.

Save the date: Next joint UNICEF, UNFPA and WHO meeting with
manufacturers and suppliers of in vitro diagnostics, vaccines, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products

The meeting will take place at UN City, Marmorvej 51, 2100 Copenhagen, Denmark. Registration is now open. Manufacturers can request face-to-face meetings with our team to discuss potential or current applications, or to seek clarification on any aspect of IVD prequalification. Requests should be sent to diagnostics@who.int.

Please visit this page for more information. We look forward to seeing you all there.

Recently WHO-prequalified IVDs

For more information on these recently prequalified products, click on the product of interest in the table below.

<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>Xpert® HCV Viral Load</td>
<td>GXHCV-VL-CE-10</td>
<td>Cepheid AB</td>
<td>04 April 2017</td>
</tr>
<tr>
<td>Geenius™ HIV 1/2 Confirmatory Assay with Geenius™ HIV1/2 Confirmatory Controls</td>
<td>72460, 72329</td>
<td>Bio-Rad</td>
<td>17 March 2017</td>
</tr>
<tr>
<td>OraQuick HCV Rapid Antibody Test Kit</td>
<td>1001-0270, 1001-0274</td>
<td>OraSure Technologies, Inc.</td>
<td>1 March 2017</td>
</tr>
</tbody>
</table>

For the complete list of prequalified in vitro diagnostics, please refer to: http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

Update: alternative performance evaluation mechanism

The alternative performance evaluation mechanism is well under way. WHO announced its introduction in June 2016 as part of improvement measures in response to issues raised by stakeholders. Since then, expressions of interest (EOI) have been received from 12 institutions around the world. As of May 2017, seven audits had been conducted and four laboratories listed as WHO Prequalification Evaluating Laboratories. The list of laboratories is available here.

The mechanism is enabling WHO to implement earlier scheduling of performance evaluations, which is expected to reduce timelines to prequalification for newly submitted applications.
To subscribe or unsubscribe to the Prequalification of In Vitro Diagnostics Update, send an email to diagnostics@who.int with subscribe or unsubscribe in the subject.

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