Important reminder on changes to procurement eligibility for malaria RDTs

On 8 December 2017, we announced that as of 1st January 2018, all malaria rapid diagnostic tests (RDTs) that diagnose P. falciparum-only through detection of histidine rich protein 2 (HRP2) must be prequalified by WHO in order to be eligible for WHO procurement. The prequalified list of malaria RDTs is available here.

For all other types of malaria RDTs, the procurement requirements will remain the same: valid ISO 13485:2003 certification, submission to WHO prequalification and meeting performance requirements in the latest round of WHO Product Testing of malaria RDTs, until 1 July 2018. At that time, it is expected that more non-HRP2 malaria RDTs will have successfully been prequalified.

The WHO prequalification Team will continue to accept new applications for all types of antigen-detecting malaria RDTs.

Recently WHO-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>Xpert® HPV</td>
<td>GXHPV-CE-10</td>
<td>Cepheid AB</td>
<td>21 December 2017</td>
</tr>
<tr>
<td>Aptima™ HIV-1 Quant Dx Assay</td>
<td>PRD-03000 (PRD-03002, PRD-03001), 303014 and PRD-03003</td>
<td>Hologic, Inc.</td>
<td>21 December 2017</td>
</tr>
<tr>
<td>SD BIOLINE HBsAg</td>
<td>01FK10W</td>
<td>Standard Diagnostics, Inc.</td>
<td>22 December 2017</td>
</tr>
<tr>
<td>Genie™ Fast HIV 1/2</td>
<td>72327, 72347, 72330</td>
<td>Bio-Rad</td>
<td>22 December 2017</td>
</tr>
</tbody>
</table>
The prequalification of SD BIOLINE HBsAg represents a significant milestone for WHO as it is the first rapid diagnostic test (RDT) for the detection of hepatitis B surface antigen (HBsAg) to be WHO prequalified. WHO expects the use of quality assured HBsAg RDTs to increase access to hepatitis B testing, especially in resource-limited settings, allowing a better linkage to prevention, care and treatment services and facilitating the implementation of newly published WHO guidelines on hepatitis testing.

Xpert ® HPV assay is the first HPV nucleic acid testing (NAT) technology to be prequalified by WHO. This represents a great advance for WHO’s efforts to detect, treat and prevent cervical cancer. The assay is intended to be used with any of Cepheid’s GenXpert® systems, some of which can be used at or near to the point of care. This is expected to increase access to HPV testing for women in a variety of settings, including in regions with lower resources.

Additional guidance

The Expert Committee on Biological Standardization (ECBS) which met in Geneva from 17 to 20 October 2017 has approved the Technical Guidance Series (TGS) for WHO prequalification of in vitro diagnostic medical devices for establishing stability of in vitro diagnostic medical devices (TGS-2). The document approved by the ECBS can be accessed here.

We would also like to remind you that the document “TGS 7 Risk management for manufacturers of in vitro diagnostic medical devices” is still available for public comment. This document was developed to aid manufacturers of IVDs to develop appropriate risk management within their quality management system prior to compiling a product dossier for submission to WHO and in preparation for the site inspection component of the WHO prequalification assessment.

Comments will be taken into consideration if submitted to diagnostics@who.int no later than 25 January 2018 using the comments table available on our website.

Update on WHO Prequalification Evaluating Laboratories
The work undertaken to expand the network of partner laboratories with experience and capabilities to conduct performance evaluations of IVDs for the purpose of WHO prequalification assessment has continued over the last year. To this date, we have received a total of 14 expressions of interest from institutes and laboratories all over the world. Ten audits have been conducted and nine institutions have been listed. Currently listed laboratories are capable of performing evaluations for most of the IVD analytes included in the scope of prequalification assessment including: HIV serology and NAT, CD4 enumeration technologies, hepatitis C serology and NAT, hepatitis B surface antigen and HIV/syphilis serology.

The list of currently listed laboratories is available here.