WHO Prequalification Financing Model – fees for in vitro diagnostics

A new fee system will come into force on 1st of August 2018 for the prequalification assessment of in vitro diagnostics, in line with modifications made to the fee system for WHO prequalification of vaccines and medicines introduced in 2017. The new system aims to ensure the sustainability and quality of prequalification assessment services provided to WHO Member States and external partners.

A public consultation on the fee system was held earlier this year; a summary of the comments received and the outcome of the consultation can be found here.

<table>
<thead>
<tr>
<th>Fees for prequalification assessment as of 1 August 2018</th>
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<tbody>
<tr>
<td><strong>Single assessment fee per product</strong></td>
</tr>
<tr>
<td>US$ 5 000 for dossier screening AND US$ 12 000 for review</td>
</tr>
</tbody>
</table>

Any queries regarding the new fees should be directed to diagnostics@who.int.

Recently WHO-prequalified IVDs
We are very pleased to announce the prequalification of the following product:

<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>Muse Auto CD4/CD4% kit</td>
<td>MCA100101, MCA500101, MCA1XK101</td>
<td>EMD Millipore Corporation</td>
<td>24 May 2018</td>
</tr>
</tbody>
</table>

The Muse® Auto CD4/CD4% Assay is intended to be performed on a Muse® Cell Analyzer, to identify and quantify both absolute CD4 T-cell counts and CD4 percent values in venous and capillary whole blood samples. Although WHO recommends a “test and treat” approach for people with a confirmed HIV diagnosis irrespective of CD4 count, CD4 cell count testing remains essential for identifying individuals with advanced HIV disease who are eligible for a specific package of interventions and to better guide clinical management of patients presenting with virological failure. More information on WHO’s guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy can be found [here](#).

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

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

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**Call for Applications to the WHO Prequalification of In Vitro Diagnostics**

WHO is actively seeking applications for RDTs intended for:

- diagnosis of cholera
- diagnosis of malaria

In addition, following inclusion in 2016 of IVDs intended for detection of human papillomavirus (HPV) at or near the point of care, all nucleic acid-based technologies (NAT) for detection of HPV, including conventional laboratory-based platforms, are now eligible for prequalification. These IVDs are expected to greatly contribute to the efforts towards the elimination of cervical cancer.

Manufacturers are highly encouraged to submit an application for prequalification assessment. An overview of the prequalification process can be found [here](#) and the submission form can be found [here](#).

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**First Annual Meeting of the WHO Prequalification Evaluating Laboratories**
WHO held the first meeting of WHO Prequalification of Evaluating Laboratories on 12 and 13 June 2018, bringing together 25 participants representing the 11 institutions that have now been listed by WHO, as well as a number of laboratories currently undergoing assessment.

The objectives of the meeting were to:

- discuss the WHO performance evaluation processes, evaluation protocols, result templates, report templates and other standard operating procedures
- discuss communication strategies between laboratories and WHO and between laboratories and manufacturers
- introduce the WHO requirements for ensuring confidentiality and discuss? views on conflict of interest and how to mitigate it
- establish laboratory networks to facilitate specimen management.

A summary document outlining the most important outcomes of the meeting can be found here.

Laboratories interested in becoming a WHO Prequalification Evaluating Laboratory are encouraged to submit an expression of interest to WHO. Instructions on how to apply are available here.

The list of currently listed laboratories is available here.

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**Call for Public Comment: guidance on reportable changes to a prequalified male circumcision device**

WHO is requesting male circumcision device experts and other stakeholders to provide comments on the WHO guidance document Reportable changes to a WHO Prequalified Male Circumcision Device. This document provides manufacturers of WHO prequalified male circumcision devices with information on how and when they must report to WHO:

- changes to the prequalified device or its manufacture;
- changes to the quality management system (QMS) under which the device is designed and/or manufactured; and/or
- other reportable administrative changes.

All comments received using the comments table to diagnostics@who.int by 27 September 2018 will
be considered in the finalization of the draft document. Please share this information with your colleagues who may be interested in the topic.