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>CyFlow® Counter System with CD4 easy count kit and CD4% easy count kit</td>
<td>CY-S-3022 05-8401 05-8405</td>
<td>Sysmex Partec GmbH</td>
<td>8 August 2018</td>
</tr>
<tr>
<td>Vikia HBsAg</td>
<td>31124</td>
<td>bioMérieux SA</td>
<td>26 July 2018</td>
</tr>
<tr>
<td>careHPV Test</td>
<td>614015</td>
<td>QIAGEN GmbH</td>
<td>13 July 2018</td>
</tr>
</tbody>
</table>

The CyFlow® Counter System is a cell analysis system designed for the determination of the absolute number of CD4+ T lymphocytes and the percentage of CD4+ cells in whole blood specimens. CD4 cell count testing remains essential for identifying individuals with advanced HIV disease and to guide clinical management of individuals presenting with treatment failure. More information on WHO’s guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy can be found [here](http://apps.who.int/iris/bitstream/handle/10665/246177/WHO-HIV-2016.06-eng.pdf?sequence=1)

The Vikia HBsAg is a rapid diagnostic test (RDT) for the detection of hepatitis B surface antigen. It is only the second RDT prequalified for the diagnosis hepatitis B and is expected to increase access to testing in resource-limited settings, contributing to the goal of reducing viral hepatitis infections to less than 1 million and associated deaths to less than 500 000 by 2030[^1]. More information on WHO’s recommendations on hepatitis B testing can be found [here](http://apps.who.int/iris/bitstream/handle/10665/246177/WHO-HIV-2016.06-eng.pdf?sequence=1)

The careHPV Test is indicated as a primary screening tool for the detection of high risk HPV. WHO recommends a “screen and treat” approach using available screening tools such as HPV tests. The assay should increase testing for HPV in resource-limited settings, assisting in the push towards elimination of cervical cancer. Read all about the WHO Director General’s call for action towards the elimination of cervical cancer.

[^1]: GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS, 2016–2021

In addition, a change notification to for the following prequalified product was assessed and accepted:

<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>COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0</td>
<td>05212294190</td>
<td>Roche Molecular Systems, Inc.</td>
<td>8 August 2018</td>
</tr>
</tbody>
</table>

Roche Molecular Systems, Inc. submitted a change notification to the prequalified COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 in order to add the cobas® Plasma Separation Card (PSC) as an additional collection device which allows capillary whole blood collection which can then be transported and tested as a dried plasma spot. The addition of dried plasma obtained from a PSC as a specimen type bypasses the need for a phlebotomist and results in an additional specimen type that allows decentralized collection, increasing access to accurate HIV viral load testing in resource-limited settings.

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

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

**NEW GUIDANCE PUBLISHED: TGS 7 Risk management for manufacturers of in vitro diagnostic medical devices**

Continuing its efforts to support manufacturers of IVDs wishing to submit a product for prequalification assessment, WHO has published an additional guidance document under its Technical Guidance Series: "**TGS 7 Risk management for manufacturers of in vitro diagnostic medical devices**". This document will assist manufacturers of IVDs in developing appropriate risk management within their quality management system. In addition, it will support manufacturers in fulfilling risk management requirements for a product dossier and in preparing for the site inspection component of the WHO prequalification assessment.

**CALL FOR PUBLIC COMMENT: TSS 6 Syphilis Rapid diagnostic tests**
We would like to invite you to review the draft document posted on the WHO Prequalification – Diagnostic Assessment website under Guidance and training on 24 September for public comment. Public comments must be received to diagnostics@who.int before 23 November 2018 using this comments table to be considered in the final version of the document.

**TSS-6 Syphilis Rapid diagnostic tests** is being developed for manufacturers of rapid diagnostic tests used to detect syphilis who are interested in applying for WHO prequalification assessment. The technical specifications document outlines the minimum performance studies necessary to meet for WHO Prequalification requirements.

The working document has been drafted based on the outcome of several discussions, external reviews and a technical consultation with external stakeholders.

**DEADLINE EXTENDED: Guidance on reportable changes to a prequalified male circumcision device**

WHO is still considering comments to the 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 changes to WHO:

All comments received using the comments table to diagnostics@who.int by 31 October 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.

**NEW IT PLATFORM FOR SUBMISSION AND MANAGEMENT OF PREQUALIFICATION APPLICATIONS**

The WHO Prequalification of In Vitro Diagnostics will be implementing a new IT platform over the next few months to manage prequalification submissions and interactions with manufacturers and external partners, including product dossier assessors and WHO Prequalification Evaluating Laboratories.
From Q1 2019, applications will be managed electronically through a dedicated online system. Pre-submission forms will be phased out and manufacturers new to WHO Prequalification will be required to attend pre-submission meetings to ensure an understanding of the process prior to submission. Manufacturers will be required to complete forms online and upload required documentation as instructed by the system. The new system will provide a more efficient management of applications as well as a more efficient platform to monitor and evaluate performance of WHO and manufacturers.

The system will be launched at the beginning of 2019. Further information will be distributed in advance of the launch.