New guidance

Technical Specifications Series

WHO is developing a Technical Specifications Series (TSS) for WHO prequalification of IVDs.

The main objective of this series is to provide manufacturers with detailed performance requirements, so they can meet WHO expectations. The documents provide further transparency about the prequalification assessment. Specifications have been developed in alignment with best international regulatory practice and take into consideration the specific needs of WHO Member States, particularly in resource-limited settings.

The first document in the series — entitled *Technical specifications for WHO prequalification of Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing* — is aimed at manufacturers of rapid diagnostic tests (RDTs) for the detection of HIV, including those intended for self-testing and those designed to detect HIV and additional analytes (e.g. HIV/syphilis). The document describes minimum performance requirements for prequalification; where possible, these have been aligned with published guidance, standards and/or regulatory documents. That said, given WHO’s focus on resource-limited settings, additional conditions are described and explained. The document is available for public comment until 15 November 2016.

WHO manual for organizing a national EQA programme for health laboratories and other testing sites
External quality assessment (EQA) ensures that testing is performed accurately, results are reproducible, and errors detected and corrected to avoid incorrect diagnosis. EQA usually takes the form of participation in EQA schemes (also called proficiency testing). These include follow up on any unacceptable EQA results, with implementation of corrective actions. EQA is an essential part of a functional quality management system.

WHO has developed a manual describing some of the strategic, managerial, financial, technical and scientific aspects that need to be considered when establishing a national EQA programme for clinical laboratories and other testing services all health care levels. The manual is intended for ministries of health, programme managers, laboratory managers, testing personnel and other implementing partners and EQA providers.

**Upcoming events**

**International Conference of Drug Regulatory Authorities (29 November – 02 December 2016, Cape Town, South Africa)**

The International Conference of Drug Regulatory Authorities (ICDRAs) bring regulatory authorities of WHO Member States together in an effort to foster collaboration, exchange information and develop common approaches to shared issues. While the focus of ICDRAs has been on medicines, medical devices, including IVDs, and their regulation are stimulating increasing global interest and have gained a well-warranted place on the ICDRA agenda.

One plenary session and two workshops dedicated to medical devices regulation are scheduled. More information can be found here.

**WHO workshop on post-market surveillance of in vitro diagnostics (IVDs) for testing providers and regulators (29–30 November 2016, Cape Town, South Africa)**

The deficiencies of regulatory oversight for in vitro diagnostics (IVDs), both for pre-market assessment and post-market activities, are widely acknowledged as hindering efforts to ensure the safety, quality and performance of IVDs. Post-market information on IVDs empowers end-users to detect issues, and for national regulatory authorities to investigate, communicate and contain events that threaten public health security, and for authorities to take appropriate action.

This workshop will focus on developing the skills of end-users (testing providers) and
regulators to conduct post-market surveillance for IVDs. It will help participants to draft a plan of action to be implemented upon return to their country.

**African Society for Laboratory Medicine (ASLM) 2016 (3–8 December, Cape Town, South Africa)**

The ASLM conference is a biennial event that provides a platform for the international community of laboratory medicine to come together and share relevant scientific breakthroughs and possible approaches for tackling common global health issues.

WHO Prequalification of In Vitro Diagnostics will be holding the following seminars:

- WHO workshop on post-market surveillance of IVDs (for end-users) and external quality assessment schemes.
- Ensuring the quality of in vitro diagnostics (IVDs): WHO Prequalification of IVDs (PQDx) and Emergency Use Assessment and Listing (EUAL).
- WHO workshop on Prequalification of In Vitro Diagnostics (IVDs) for national regulatory authorities.

More detailed information about times and places will be circulated before the conference. More information on ASLM2016 can be found [here](http://www.who.int/diagnostics_laboratory/en/).

**Newly listed product under the Emergency Use Assessment and Listing (EUAl) procedure.**

WHO is happy to announce the listing of the first IVD intended for the detection of Zika virus under the EUAl procedure. The **RealStar® Zika Virus RT-PCR Kit 1.0**, product code REF – 591013 manufactured by altona Diagnostics GmbH, Mörkenstraße 12, 22767 Hamburg, Germany, CE marked regulatory version was listed on 5 August 2016. Two additional IVDs are expected to be listed in Q4 2016.

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