WHO Prequalification Of In Vitro Diagnostics

1st Invitation to Laboratories to submit an Expression of Interest (EOI)

WHO invites laboratories with experience in conducting independent performance evaluations of in vitro diagnostics (IVDs) which assist in the diagnosis and/or monitoring of infection with HIV-1/HIV-2, syphilis, hepatitis B, hepatitis C, Human Papillomavirus (HPV) and G6PD to submit an Expression of Interest (EOI) for WHO Prequalification Evaluating Laboratories.

Aim of this process:

The aim of the invitation is to encourage laboratories to submit an application for assessment against WHO requirements and international standards for conducting independent performance evaluations of IVDs for prequalification purposes. Laboratories that meet the established requirements will be listed as WHO Prequalification Evaluating Laboratories.

Basis for this invitation:

The WHO prequalification process requires those manufacturers of IVDs having applied for WHO Prequalification, to submit their product(s) for laboratory performance evaluation by a WHO Prequalification Evaluating Laboratory. The process for assessment of WHO IVD Performance Evaluation Sites is provided in SOP_PQDx 248: The assessment Process for Listing of WHO Prequalification Laboratories for IVD is described here.

Laboratory Eligibility:

- Participation in this assessment process is voluntary.
- This invitation is not limited to laboratories from a specific region. However, WHO reserves the right to prioritize the assessment of laboratories in the following order:

1. WHO collaborating centres and laboratories currently supporting WHO prequalification performance evaluations in order to ensure continuity of work;
2. National laboratories or laboratories that provide testing services to the government in their respective country; and
3. Laboratories located in geographical areas corresponding to the intended setting of use of the IVDs submitted for assessment.

Submission of an EOI:

All information must be submitted in English. Laboratories interested in being assessed under this procedure must provide WHO with:

1. An EOI letter expressing interest to be listed as a WHO Prequalification Evaluating Laboratory providing two authorized contacts and confirming that the submitted EOI submission form is complete and correct.
2. A completed EOI submission form with requested attachments.

One hard copy and one electronic copy of the above mentioned documentation must be sent to the following address:

WHO Prequalification Team - Diagnostics
20 Avenue Appia
1211 Geneva 27 Switzerland

Assessment procedure following submission of an EOI by a laboratory:
The process of assessment of the candidate laboratories by WHO consist of the following, as specified in PQDx_248 to assess compliance with WHO requirements:

1. Receipt of an EOI
2. Stage 1 audit- Assessment of EOI and specific quality management system documentation
3. Stage 2 audit- On site audit of the laboratory; and
4. Listing of successful laboratories as WHO Prequalification Evaluating Laboratories

Outcome of assessment procedure:
If the assessment demonstrates that a laboratory meets WHO requirements, it will be listed as a WHO Prequalification Evaluating Laboratory to conduct performance evaluations in the contest of prequalification for a time period specified by WHO.

Re-assessment of laboratories and monitoring of complaints:
Once a laboratory is listed , ongoing monitoring will require:

1. Audits at regular intervals (at least once every three to five years);
2. Monitoring to ensure ongoing compliance with WHO requirements and relevant standards; and
3. Submission of an annual External Quality Assessment (EQA) Scheme/Proficiency Testing (PT) report for the scope of listing

WHO may delist a WHO performance evaluation site when there is evidence of non-compliance with WHO requirements and/or international standards.

For more information on the WHO Prequalification Team - Diagnostics, visit the WHO PRequalfiicationof IVDs website.. If you have any questions relating to the procedure email diagnostics@who.int

References:

- ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories. Geneva, Switzerland; 2005. International Organization for Standardization/ International Electrotechnical Commission.

- ISO 15189:2012 Medical laboratories - Requirements for quality and competence. Geneva, Switzerland; 2012. International Organization for Standardization.