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**WHO Prequalification Evaluating Laboratories**

 **5-6 November 2019, Salle D, WHO HQ, Geneva**

**Meeting background**

The independent laboratory performance evaluation of in vitro diagnostics (IVDs) submitted for prequalification enables WHO to verify the performance characteristics that are considered essential for their use in resource-limited settings. In order to further streamline the prequalification assessment, WHO has developed an alternative performance evaluation mechanism providing the manufacturers with two options to fulfil the performance evaluation requirement of the prequalification assessment. In option 1, the performance evaluation is coordinated and financed by WHO while in option 2 the performance evaluation is coordinated, and its cost borne by the manufacturer. WHO invited laboratories with experience in conducting independent performance evaluations of IVDs to submit an Expression of Interest (EOI) to become a WHO Prequalification Evaluating Laboratory (PEL). Laboratories having fulfilled initial requirements were audited against WHO requirements based on ISO 15189:2012 and/or ISO 17025:2005 to assess their competencies. Currently, 14 laboratories have been listed as WHO prequalification evaluating sites.

A first meeting of WHO Prequalification Evaluating Laboratories was organized in June 2018. During this meeting, a number of challenges faced by PELs in the organization of performance evaluations and possible solutions were discussed, which led to a list of action points[[1]](#footnote-1). The aim of this second meeting of PELs is to follow up on these action points, continue the discussion on challenges faced by PELs and review revised protocols for performance evaluations of serology/antigen and molecular assays.

**Meeting objectives**

1. To discuss WHO Performance evaluation processes and labs’ experience with the alternative performance evaluation mechanism, including communication strategies with WHO and manufacturers.
2. To review revised protocols, result templates, report templates and other operating procedures.
3. To discuss about the next steps to allow sample sharing between WHO Prequalification Evaluating Laboratories.

**Meeting outcomes**

1. Action points for continued improvement of the organization of performance evaluations
2. Proposal for sample sharing between laboratories
3. Feedback on revised performance evaluation protocols
1. https://www.who.int/diagnostics\_laboratory/evaluations/180627\_meeting\_report\_1st\_evaluating\_laboratories.pdf [↑](#footnote-ref-1)