

DEVELOPMENT OF TUBERCULOSIS DIAGNOSTICS ADVICE TO MANUFACTURERS

DEVELOPMENT AND ASSESSMENT OF TB DIAGNOSTICS



GUIDELINE DEVELOPMENT PROCESS FOR TUBERCULOSIS DIAGNOSTICS

- For the development of guidelines on TB diagnostics WHO uses the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach to assess the quality of a body of evidence, and to develop and report recommendations.
- The detailed policy recommendations referred to in guidelines qualify their strength as well as the certainty of the evidence on which they are based.
- Four main factors determine the direction and strength of a recommendation in public health
 - \circ The quality of the evidence
 - \circ \quad Values and preferences related to the outcomes of an intervention or exposure
 - The balance of evidence and harms
 - Resource implications

GENERAL ADVICE

- Engage with WHO early in the development process to ensure that design-locked products meet WHO requirements
- WHO provides information on reference standards, which samples should be tested, how the evaluation of diagnostics differs from that of medicines, and provides general guidance on study design.
- FIND as a WHO Collaborating Center facilitates independent evaluation.
- WHO will consider an evaluation of any new test that meets the minimal performance characteristics of any of the priority TPPs.
- WHO evaluates different diagnostics in the settings of intended use including centralised, decentralised and near point-of care settings, as relevant.
- WHO, FIND, UNITAID, StopTB Partnership, McGill University all play a role in accelerating TB diagnostic through the TB diagnostic critical pathway http://www.tbdxpathway.org/



DO TB DIAGNOSTICS NEED WHO PRE-QUALIFICATION (PQ)?

Currently PQ is not applicable to TB diagnostic tests

- All WHO recommended TB diagnostics are automatically included in the Essential Diagnostics List
- Most TB diagnostics have single source manufacturers employing unique technologies
- TB diagnostic guidelines specify the use of TB tests in specific patients populations
- TB diagnostics usually involve a multi-step laboratory-based process (with pre-analytical, analytical and post-analytical phases)

The PQ process currently applies to *in-vitro* diagnostics (IVDs) for HIV, Malaria and other infectious diseases, and involves:

- Review of the product dossier
- Performance evaluation including operational characteristics
- Inspection of manufacturing sites and
- Labelling review

CONSOLIDATED GUIDELINES ON TB DIAGNOSTICS, TREATMENT AND CARE



This document consolidates all TB diagnostic guidelines into a single document.





The Compendium of WHO guidelines and associated standards are available (click <u>here</u>)

This document consolidates all TB diagnostic, treatment and care guidelines and standards into a single document.

For more information please visit: http://www.who.int/tb © World Health Organization, May 2018