Prequalification of In Vitro Diagnostics

September 2024

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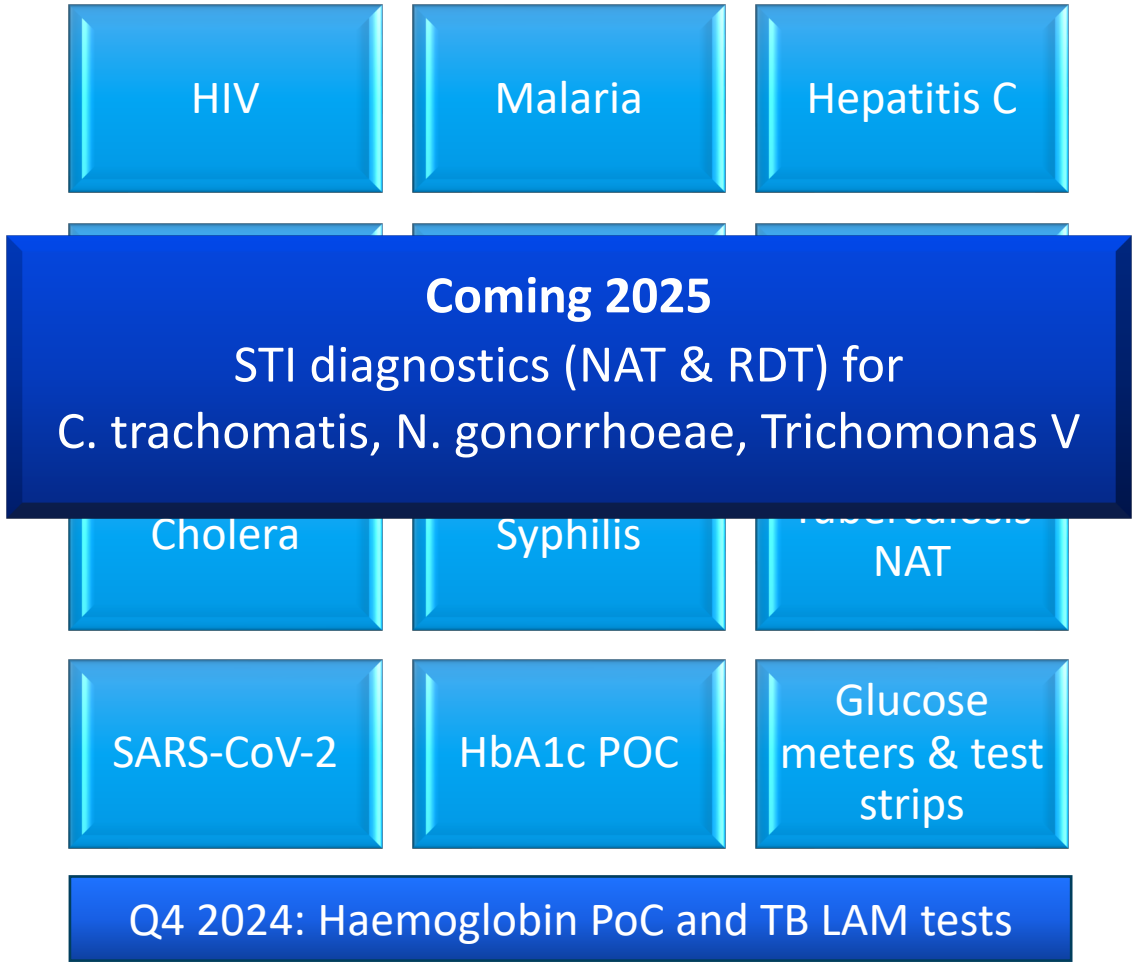
PQ of IVDs: Aim & Scope

- The aim of PQDx is to promote and facilitate **access** to safe, appropriate and affordable IVDs of good quality
- Focus is placed **on IVDs for priority diseases** and their suitability for use in **resource-limited settings**
- The **scope** of IVDs eligible for PQ continues to expand
- Nine IVDs listed in 2024 so far
  - Currently 114 IVDs prequalified
- PQ List available on website: https://extranet.who.int/prequal/vitro-diagnostics/prequalified-vitro-diagnostics



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WHO PQ Technical Specifications Series (TSS)

- TSS developed in alignment with relevant international and national standards, literature and best practise (e.g., CLSI, IMDRF, FDA, ISO ..)
  - Consultation with WHO programme and external experts
  - Deviations related to suitability in resource limited settings (RLS)
- Each TSS document is tailored to a specific pathogen/type of assay
  - Requirements that address needs of Member States in LMIC
  - Requirements that relate to general performance characteristics
- Summarize minimum performance requirements for WHO prequalification, to establish:
  - Performance validation criteria
  - Appropriate reference methods and reference materials

➢ Clarify PQ requirements for manufacturers and assessors

NEW TSS in Development

TSS 24 – IVDs for the qualitative detection of *Neisseria gonorrhoeae, Chlamydia trachomatis* and *Trichomonas vaginalis* nucleic acid

TSS 25 - Rapid diagnostic tests to detect *Neisseria gonorrhoeae* antigen

TSS 26 - Rapid diagnostic tests to detect *Chlamydia trachomatis* antigen

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https://extranet.who.int/prequal/vitro-diagnostics/technical-specifications-series

Technical guidance series documents (TGS)

- IVD Stability
- Principles of performance studies
- Test method validation
- Instructions for Use (IFU)
- Quality assurance and quality control panels
- Risk management
- Quality control

- Cover broad principles related to validation and verification of an IVD
- Provide detailed guidance with examples relevant for PQ assessment
- Reflect lessons learned and not a requirement

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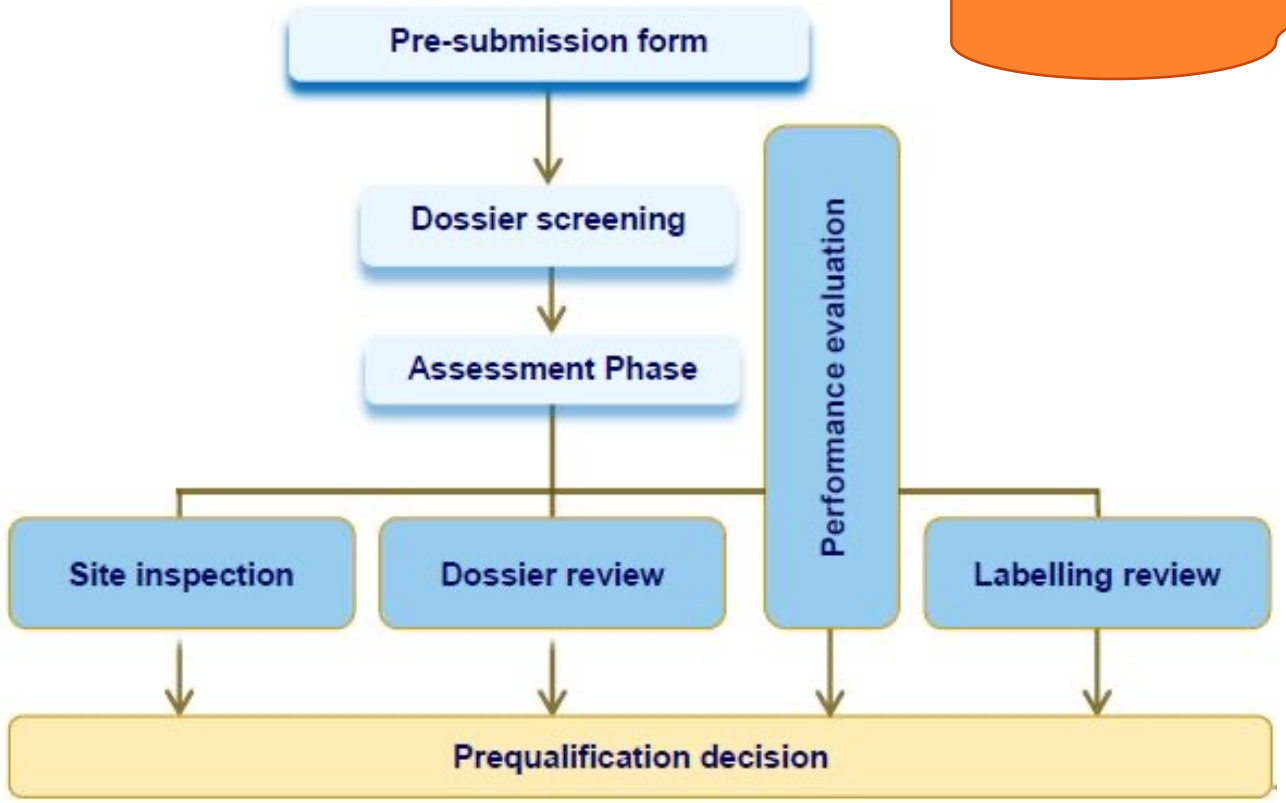
https://extranet.who.int/prequal/vitro-diagnostics/technical-guidance-series

PQ Application Process

UPDATE
Process changes planned with public consultation Q4 2024



Pre-submission

- Manufacturer completes the pre-submission form
- WHO schedules a pre-submission meeting
- WHO screens the pre-submission form to determine if product is eligible & type of assessment (full or abridged)

PQ assessment

- Review of product dossier (full or abridged)
- Performance evaluation
- Site Inspection
- Labelling review

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Product dossier assessment

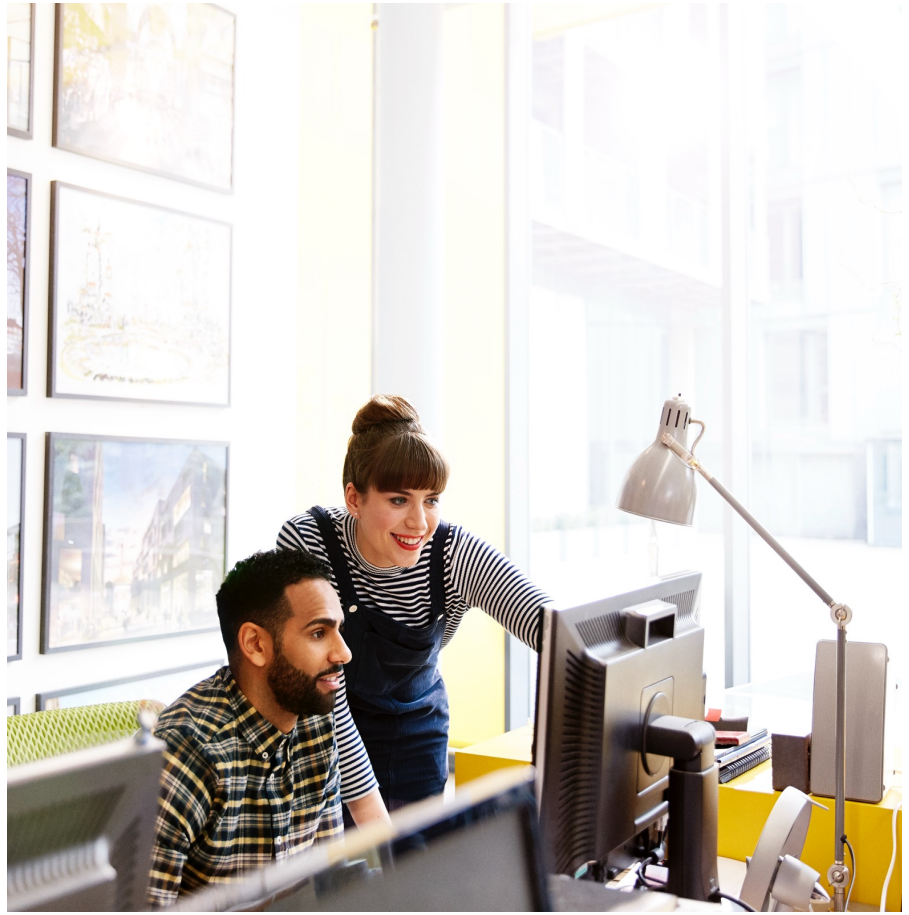
Technical review of manufacturer's evidence of quality, safety & performance

- Performed by subject matter experts

- Analyzing the relevance of the data in the dossier
  - Reliable data that supports the manufacturers claims of quality, safety and performance
  - Appropriate & well-designed validation studies
- Review of completeness, accuracy and consistency of data
  - From initial product design, through validation, manufacture, quality control and release onto the market

➢ Are the specifications in the TSS met?

➢ Has the manufacturer considered IVD use in RLS?



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Dossier review process

IMPORTANT
Maximum of 6 months extension time available

- Manufacturer submits dossier to WHO
- Dossier screened for completeness
- Dossier sent to subject matter expert for technical review
- Expert provides completed dossier review checklist and notes any deficiencies in the dossier
- WHO prepares dossier review letter for manufacturer requesting additional information or clarifications
- Manufacturer submits corrective action plan (CAP)
  - Further clarification may be required of manufacturer's responses to requests for information
  - 2 rounds of CAP are possible

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Performance evaluation

Independent **verification** of the performance of IVDs submitted for prequalification assessment

- Assays are challenged with a focus on their use in resource-limited settings and in the context of WHO guidelines
- A standard PQ protocol is followed for the evaluation
  - May include analytical, clinical & operational performance
  - The dataset obtained complements the verification and validation data submitted by the manufacturer in the product dossier
  - Currently takes place in a WHO Collaborating Centre and/or a designated Performance Evaluation Laboratory (PEL)
- Manufacturers can choose:
  - Option 1: PEL selected by WHO & PE paid for by WHO
  - Option 2: PEL selected by Mx & PE paid for by Mx

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Manufacturing site inspection

- Evidence of a fully implemented quality management system (design & development, manufacturing including quality control, storage, distribution) based on ISO 13485
- Demonstrates that the risk management meets ISO 14971 requirements
- Consideration of the robustness of the product for WHO intended settings and users
- Evidence of sufficient capacity to ensure reliable delivery

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Prequalification decision

For IVDs that meet PQ requirements

- The product is added to the list of WHO prequalified IVDs
- The public report is prepared & published

→ IVD is eligible for WHO and UN procurement & CRP

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Collaborative Registration Procedure

Aims to accelerate country registration of prequalified IVDs through information sharing between WHO PQ and National Regulatory Authorities

PRINCIPLES

- Voluntary for Mx of prequalified IVDs
- Product sameness must be guaranteed
- Confidentiality of data shared
- Target timeline: **90 days** for NRA decision

WHO PQ REPORTS SHARED

- Dossier review & Change requests
- Site Inspection
- Performance Evaluation

CRP participating NRAs list :
https://extranet.who.int/prequal/vitro-diagnostics/collaborative-procedure-accelerated-registration

Target time for NRA decision: **90** days

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Keep updated with the PQ-IVD webpage

https://extranet.who.int/prequal/vitro-diagnostics

PQDx webinars

- Keeping you informed on ongoing work, new developments, etc.
- Upcoming Webinars:
  - Change request guidance
  - Regulatory reliance in PQ (CRP)
  - Applying for PQ

PQDx Regional Workshops

- IVD Manufacturers in Africa – Kigali June 2024
- **NEXT:** IVD Manufacturers in Asia – planned for Q1 2025

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Thank you

diagnostics@who.int

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