WHO Expert Review Panel for NTD diagnostics (ERPD NTD)

Dr Hye Lynn Choi
WHO Prequalification Unit/Medicines
5-6 December 2024

Regulatory framework for NTD diagnostics

- NTD diagnostics not currently in the scope of WHO PQ
- Not realistic to include all NTD diagnostics in scope of WHO PQ
- Little incentive for manufacturers to consider WHO PQ or stringent regulatory assessment for NTD-IVDs
- WHO PQ not appropriate for lower risk diagnostics

Risks for NTD programmes

Many in lower risk classes have no such independent quality assurance.

This creates financial, reputational & programmatic risks for procurers, donors & national disease control programmes.

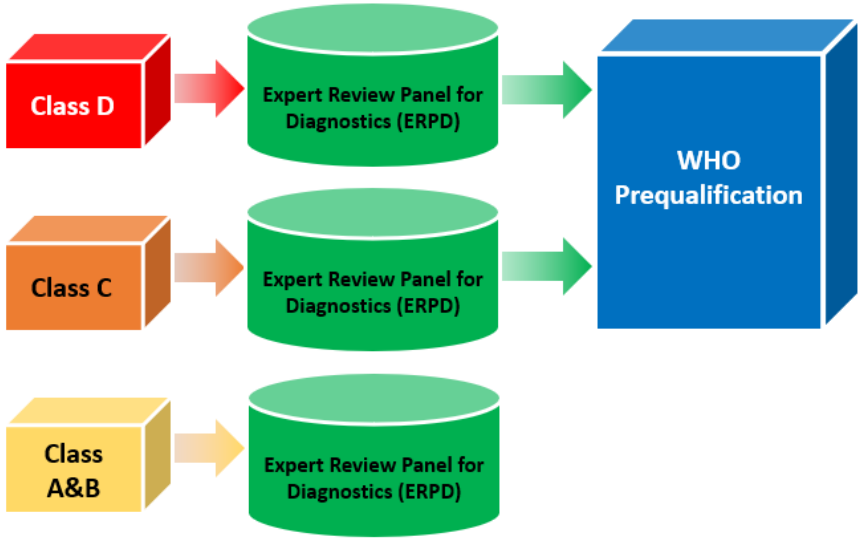
Proposed mechanism ERPD for NTD

Expert Review Panel for Diagnostics (ERPD): Risk benefit assessment of diagnostics by an independent advisory body of technical experts, coordinated by PQ

Table 4. Risk classification.

Risk classification	Diagnostics
A	None
B	Lymphatic filariasis RDT, yaws RDT, yaws NAT, soil-transmitted helminth microscopy kits, schistosomiasis RDT, schistosomiasis EIA, schistosoma microscopy kits, onchocerciasis RDT, onchocerciasis EIA, loiasis RDT
C	Dengue RDT, dengue EIA, echinococcosis RDT, echinococcosis EIA, human African trypanosomiasis RDT, human African Trypanosomiasis NAT, visceral leishmaniasis, cutaneous leishmaniasis, loiasis NAT, Buruli ulcer RDT, Buruli ulcer NAT
D	Chagas disease RDT, Chagas disease NAT

(A) RDT, Rapid diagnostic tests; EIA, enzyme immunoassay; NAT, nucleic acid test. (B) This table does not include diagnostics that were excluded from this analysis (i.e. scabies, leprosy, trachoma).



Choi HL, Ducker C, Braniff S, Argaw D, Solomon AW, Borisch B, et al. (2022) Landscape analysis of NTD diagnostics and considerations on the development of a strategy for regulatory pathways. PLoS Negl Trop Dis 16(7): e0010597. https://doi.org/10.1371/journal.pntd.0010597

Pilot ERPD for NTDs

WHO introduces new pilot scheme for Expert Review Panel for Diagnostic Products for neglected tropical diseases

10 October 2023 | Departmental news | Geneva (Reading time: 1 min (382 words)

The World Health Organization (WHO) is taking a significant step to address challenges in diagnostics for neglected tropical diseases (NTDs) by introducing a pilot scheme for a WHO Expert Review Panel for

Related

- Expert Review Panel for Diagnostic for Products

Launched for Lymphatic filariasis and Visceral leishmaniasis in September 2023

Product name	Type of Product	Manufacturer	ERPD risk category	Valid until
STANDARD Q Filariasis Ag Test	Rapid filariasis Ag diagnostic test for detection of W. bancrofti antigens	SD Biosensor, Korea	2	31 May 2025
IT Leish	Rapid test for VL diagnostic	Mologic, UK	3	31 May 2025

Outcomes of ERPD:

To advise WHO to recommend or purchase, or to not recommend or purchase, particular diagnostics for NTD programmes.

- Risk category 1 or 2: No objection to time-limited procurement
- Risk category 3: objection to procurement but the product may be considered when there are no alternatives, and provided the benefit outweighs the risk
- Risk category 4: Objection to procurement

ERPD for dengue

- Invitation launched in May 2024.
- Of 35 applications received,11 products are submitted for the assessment.
- ERPD outcomes from Round 1 assessment to be communicated to applicants

Risk category (from R1 assessment)	RDTs	NAAT tests	Enzyme immunoassay tests
Risk category 1&2	0	1	0
Risk category 3	1	2	0
Risk category 4	3	2	2

Invitation to Manufacturers of diagnostic products for diagnosis of dengue, to Submit an Expression of Interest for Product Evaluation by the WHO Expert Review Panel for Diagnostic Products

Deadline: 07 July 2024

23 May 2024 | Expression of interest

Reference of the ERPD Round: 24-NTD-0003

Concerning Diagnostic Tests for: **Dengue infections**

A. Background

WHO supports the procurement of diagnostic products and related laboratory items for the diagnosis and management of many communicable and non-communicable diseases. The landscape of in-vitro diagnostics (IVDs) has blind spots particularly for emerging diseases and zoonoses with epidemic and pandemic potential and in the field of Neglected Tropical Diseases (NTD) diagnostics . In other areas IVDs are rapidly evolving. Both situations pose significant challenges to procurers, health-care programmes, and authorities for public health and patient care. these challenges are compounded by revisions to regulatory frameworks that can

Lessons Learned

- Feedback received on the need for a user guide for ERPD dossier preparation/set of minimum requirements.
- Thorough screening needed before submission to the panel.
- ERPD outcomes to be publicly available, implications on uptake of the product for programmes, partners, procurers or member states.
- Challenges in identifying technical reviewers with comprehensive knowledge of the disease.

Next steps

- Expression of Interest (EOI) for NTD diagnostics to be published, when the programme (in consultation with DTAG) sees a need. → Encourage manufacturers to interact with NTD programmes early on!

- NTD IVDs with higher risk classification (Class A and B) may be included in the scope of WHO PQ, pending ERPD outcomes.

- A follow up NTD workshop planned in Q4 2025, South Korea.

Thank you!

https://extranet.who.int/prequal/

hchoi@who.int