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INSPIRE Health Forum

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Building agile regulatory systems for timely access to diagnostics in public health emergencies

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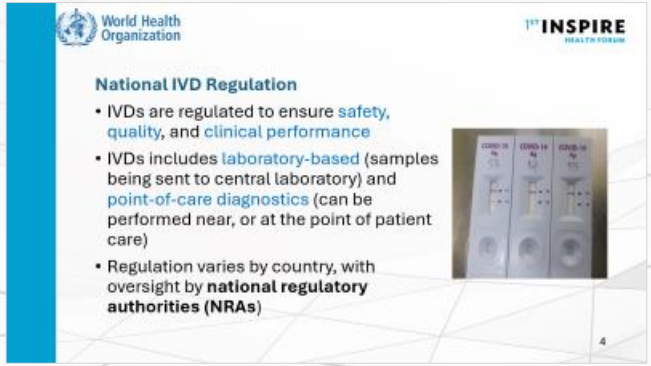
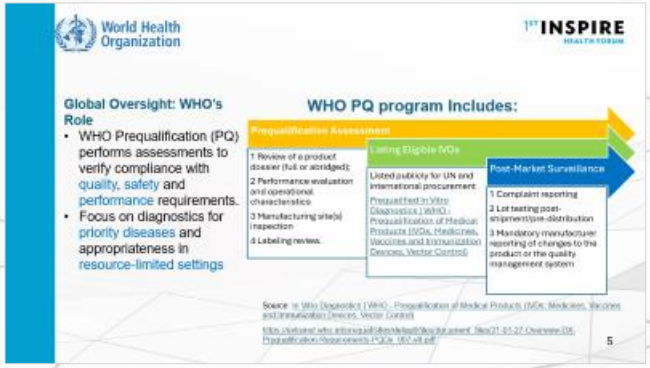
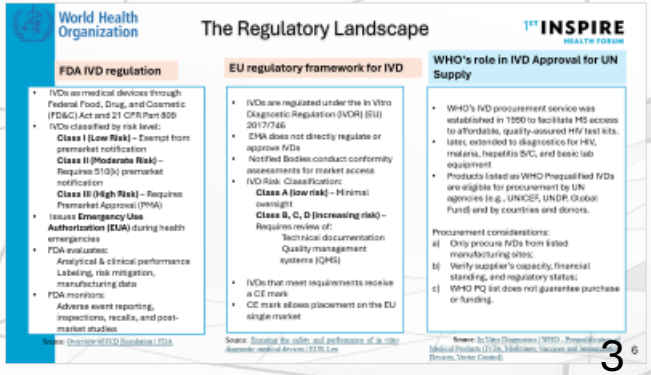
#1 How are in vitro diagnostics (IVDs) for infectious diseases regulated at national and global levels?

1.1 What role do regulatory authorities, such as FDA and EMA, play in IVD approval?

1.2 What role do WHO play in IVD approval for UN supply?

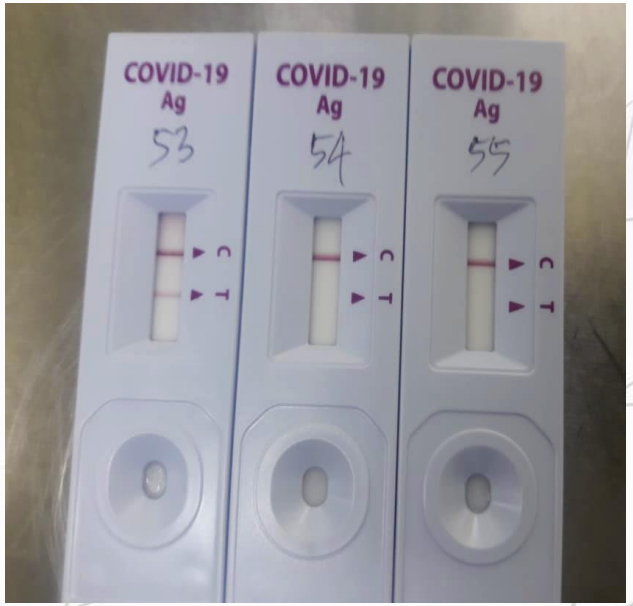






National IVD Regulation

- IVDs are regulated to ensure safety, quality, and clinical performance
- IVDs includes laboratory-based (samples being sent to central laboratory) and point-of-care diagnostics (can be performed near, or at the point of patient care)
- Regulation varies by country, with oversight by **national regulatory authorities (NRAs)**



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Global Oversight: WHO's Role

- WHO Prequalification (PQ) performs assessments to verify compliance with quality, safety and performance requirements.
- Focus on diagnostics for priority diseases and appropriateness in resource-limited settings

WHO PQ program Includes:

Prequalification Assessment

1 Review of a product dossier (full or abridged);

2 Performance evaluation and operational characteristics

3 Manufacturing site(s) inspection

4 Labeling review.

Listing Eligible IVDs

Listed publicly for UN and international procurement

Prequalified In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Post-Market Surveillance

1 Complaint reporting

2 Lot testing post-shipment/pre-distribution

3 Mandatory manufacturer reporting of changes to the product or the quality management system

Source: In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

https://extranet.who.int/prequal/sites/default/files/document_files/21-01-27-Overview-DX-Prequalification-Requirements-PQDx_007-v9.pdf

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The Regulatory Landscape

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FDA IVD regulation

- IVDs as medical devices through Federal Food, Drug, and Cosmetic (FD&C) Act and 21 CFR Part 809
- IVDs classified by risk level:
  - **Class I (Low Risk)** – Exempt from premarket notification
  - **Class II (Moderate Risk)** – Requires 510(k) premarket notification
  - **Class III (High Risk)** – Requires Premarket Approval (PMA)
- Issues **Emergency Use Authorization (EUA)** during health emergencies
- FDA evaluates:
  - Analytical & clinical performance
  - Labeling, risk mitigation, manufacturing data
- FDA monitors:
  - Adverse event reporting, inspections, recalls, and post-market studies

Source: Overview of IVD Regulation | FDA

EU regulatory framework for IVD

- IVDs are regulated under the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746
- EMA does not directly regulate or approve IVDs
- Notified Bodies conduct conformity assessments for market access
- IVD Risk Classification:
  - **Class A (low risk)** – Minimal oversight
  - **Class B, C, D (increasing risk)** – Requires review of:
    - Technical documentation
    - Quality management systems (QMS)
- IVDs that meet requirements receive a CE mark
- CE mark allows placement on the EU single market

Source: Ensuring the safety and performance of in vitro diagnostic medical devices | EUR-Lex

WHO's role in IVD Approval for UN Supply

- WHO's IVD procurement service was established in 1990 to facilitate MS access to affordable, quality-assured HIV test kits.
- later, extended to diagnostics for HIV, malaria, hepatitis B/C, and basic lab equipment
- Products listed as WHO Prequalified IVDs are eligible for procurement by UN agencies (e.g., UNICEF, UNDP, Global Fund) and by countries and donors.

Procurement considerations:

a) Only procure IVDs from listed manufacturing sites;
b) Verify supplier's capacity, financial standing, and regulatory status;
c) WHO PQ list does not guarantee purchase or funding.

Source: In Vitro Diagnostics | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

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#2 What are the current minimum data requirements for registration or marketing authorization of IVDs?

Minimum Data Requirements for IVD Registration or WHO Prequalification

Regulatory authorities and WHO Prequalification require evidence in core areas:

- **Analytical Performance**
  - ✓ Accuracy, precision, limit of detection (LoD)
  - ✓ Inclusivity/exclusivity, interference, reproducibility
- **Clinical Performance**
  - ✓ Sensitivity and specificity against clinical reference standard
  - ✓ Studies in intended-use population and settings
- **Quality Management System (QMS)**
  - ✓ Compliance with ISO 13485 or equivalent
  - ✓ Manufacturing site audits or certification
- **Safety and Risk Management**
  - ✓ Risk analysis per ISO 14971
  - ✓ Evidence of safe design and labeling, including Instructions for Use (IFU)

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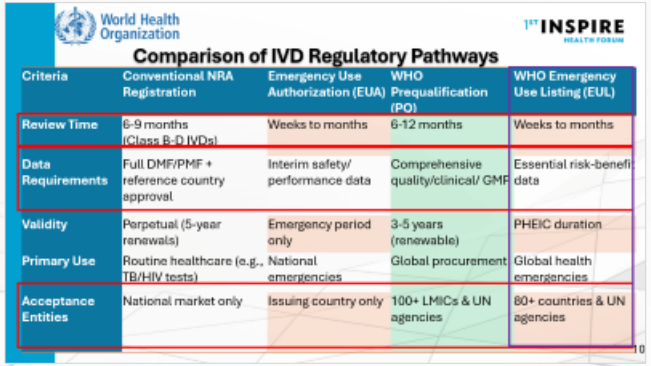
#3 What regulatory pathways exist for IVDs, including emergency and accelerated approvals?



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Comparison of IVD Regulatory Pathways

Criteria	Conventional NRA Registration	Emergency Use Authorization (EUA)	WHO Prequalification (PQ)	WHO Emergency Use Listing (EUL)
Review Time	6-9 months (Class B-D IVDs)	Weeks to months	6-12 months	Weeks to months
Data Requirements	Full DMF/PMF + reference country approval	Interim safety/ performance data	Comprehensive quality/clinical/ GMP	Essential risk-benefi data
Validity	Perpetual (5-year renewals)	Emergency period only	3-5 years (renewable)	PHEIC duration
Primary Use	Routine healthcare (e.g., TB/HIV tests)	National emergencies	Global procurement	Global health emergencies
Acceptance Entities	National market only	Issuing country only	100+ LMICs & UN agencies	80+ countries & UN agencies

10

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Mpox, PHEIC, 14 AUG 2024

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WHO lists additional mpox diagnostic tests for emergency use

News and Press Release • Source: WHO • Posted: 30 Oct 2024 • Originally published: 30 Oct 2024 • Origin: View original

As part of ongoing efforts to enhance quality-assured testing options, the World Health Organization (WHO) has listed two additional mpox in vitro diagnostics under its Emergency Use Listing (EUL) procedure. WHO's EUL is based on the review of quality, safety and performance data in compliance with international standards while addressing the specific needs of low- and middle-income countries (LMICs).

Polymerase Chain Reaction (PCR) testing, which detects viral DNA, is considered the gold standard for diagnosing mpox infection.

WHO listed the Xpert Mpox, a real-time PCR test manufactured by Cepheid under its EUL procedure, on 25 October. This test is designed for use on compatible GeneXpert systems. The Xpert Mpox test is easy to operate and delivers results in under 40 minutes. Once the cartridge is placed in the system, the process is fully automated, with real-time PCR detecting viral DNA of monkeypox virus clade II. The GeneXpert system is a near-point-of-care testing option, which can support decentralized testing.

Primary country: World
Source: World Health Organization
Format: News and Press Release
Theme: Health
Disaster type: Epidemic
Language:

Source: ReliefWeb

11

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#4 What are the distinctions in regulation between laboratory-based IVDs and point-of-care (POC) diagnostics?

- ✓How are regulatory requirements adapted for non-laboratory use diagnostics?

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Point-of-Care (POC) Diagnostics: When Regulation Meets Reality

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- **Laboratory-based IVDs** – Tests performed in centralized labs by trained technicians
- **Point-of-care (POC) diagnostics** - Tests performed near the patient, often by non-laboratory staff, therefore, POC diagnostics must ensure safety, reliability, and usability outside lab environments, often in low-resource or high-risk settings.

1. **Usability & Human Factors**
   - **WHO**: Requires usability validation with intended users (e.g., CHWs, laypersons) through comprehension testing, observation studies, and simulated use (WHO TGS-6)
   - **US FDA**: Human factors testing - FDA, Applying Human Factors and Usability Engineering to Medical Devices
   - **EU IVDR**: Requires labeling to be understandable by laypersons and tested for clarity (Regulation - 2017/746 - EN - Medical Device Regulation - EUR-Lex)

2. **Labeling and Instruction for use (IFU)**
   - **WHO:** IFU must be tested for comprehension by lay users; language should not exceed a Grade 6–8 reading level and include clear illustrations (WHO TGS-6)
   - **EU IVDR**: Labeling must be understandable by laypersons and tested for clarity (Regulation - 2017/746 - EN - Medical Device Regulation - EUR-Lex)

3. **Stability**
   - **WHO**: Requires testing at 45°C/75% RH; real-time and accelerated stability; packaging integrity testing (e.g., drop, vibration) (WHO TGS-2)

4. Differences in Regulation of POC

- **US (FDA):** POC tests are classified by complexity—moderate or CLIA-waived. Waived tests must be simple and low-risk. Design must meet FDA CLIA waiver criteria, including usability and labeling requirements.
- **EU (IVDR):** POC tests are termed near-patient tests (NPTs) and intended for use by healthcare professionals outside labs. IVDR requires usability studies, performance evaluation, and labeling adapted to user competence.

Source: Comparing U.S. and EU Regulations for Point of Care Tests | RQM+

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#5

What are post-approval process? How does Health Technology Assessment (HTA) influence regulatory and policy decisions for diagnostics?

Post-Approval Process

- **Post-Regulatory Validation Using Clinical Sample Panels**
  Many countries require local validation of IVDs post-approval, especially if approval was based on foreign regulatory reliance.

  Examples:
  - *Philippines FDA*– Require local clinical panel testing post-registration.
  - *WHO PQ* – Includes verification testing at WHO-designated laboratories.

- **Post-Approval HTAs in Well-Resourced Countries**
  Many high-income countries conduct post-market HTAs to evaluate cost-effectiveness and performance for public funding or insurance coverage.

  Typical Evaluations:
  - Cost per diagnosis or DALY/QALY averted
  - Clinical impact (e.g., earlier detection, reduced misuse)
  - Budget impact for national programs

Examples of HTA bodies in WP region

Country	HTA body	Notes
Korea (Rep.)	NECA	HTA required for NHI-covered diagnostics
Australia	MSAC	HTA required for Medicare Benefits Schedule (MBS) subsidy

- **Integrating HTA into IVD Regulatory Review**
  WHO and PATH promote “diagnostics value assessment frameworks” for LMICs.

Source: WHO - Health technology assessment of medical devices,secondedition
PATH - Dx_MarketFailures_Report_2022_v1b.pdf

#6 How is post-market surveillance (PMS) for IVDs conducted?

Post-market surveillance (PMS) for IVDs

Function	WHO Contribution
PMS system design	Technical guidance and tools for national PMS setup
PMS data collection	WHO PQ Vigilance, FIND-led lot testing, and collaborative field surveillance
Response to failures	Alert issuance, manufacturer engagement, delisting if needed
Regulatory system strengthening	Capacity building for NRAs and regional harmonization efforts
Encouraging reporting	Non-punitive, anonymous, and feedback-based approach

WHO Framework arms countries with 4 shields:

1. **Detect:** Appoint national focal points + hotlines to report a faulty test in real-time.
2. **Analyze:** Partner with WHO-designated labs (like FIND's network) for lot testing before they reach clinics.
3. **Act:** Trigger alerts within 48 hours
4. **Prevent**: Feed data back to manufacturers – turning flaws into better designs.

#7 What foundational systems and policies should be established during non-emergency periods, esp, in LMICs,
to ensure timely regulatory approval and deployment of IVDs during crises?

5 Pillars of Pandemic-Ready Diagnostics

1. National Essential Diagnostics List (NEDL) anchored in WHO Model List of Essential IVDs:

- NEDL to identify priority diagnostics for outbreak response and clinical care
- Align regulatory focus and procurement with public health needs

2. Pre-Built Emergency Pathways

- Include protocols for emergency validation, fast-track regulatory pathways, and conditional approvals, Example: FDA EUA process, and EMA's accelerated assessments (months → weeks)

3. "Regulatory 'War Rooms'

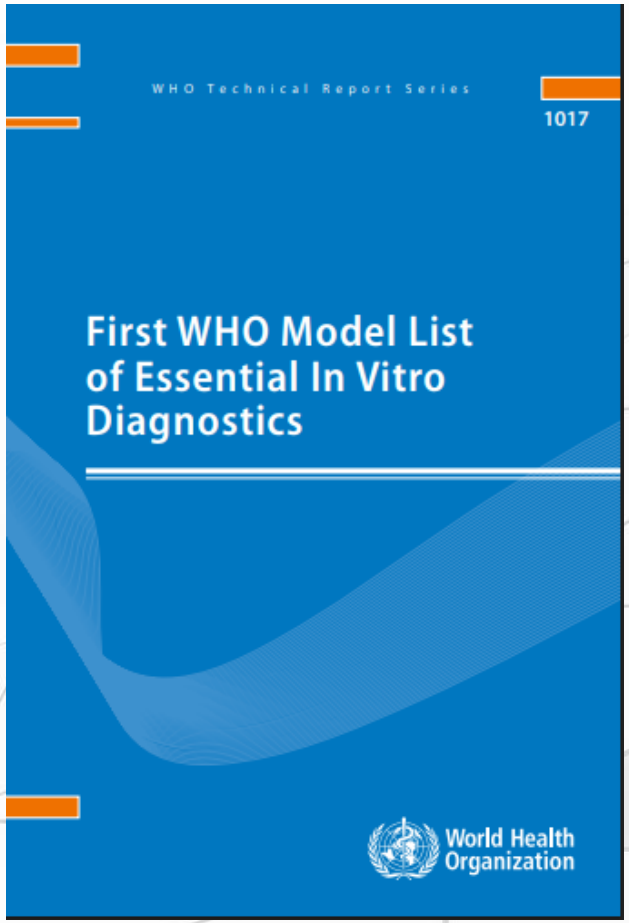
- Mutual recognition pacts, import waivers, emergency listing triggers

4. Future-Proof Capacity

- Invest in **Regulatory Science & horizon scanning** **(for novel pathogens**
- Build capacity to evaluate safety, effectiveness, and quality under pressure

5. Real-Time Intelligence Sharing

- Share real-time data on diagnostic performance, safety and regulatory decisions - Example: WHO GSRP platform



First WHO model list of essential in vitro diagnostics

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#8 How can public private partnerships and regulatory reliance mechanisms be leveraged to scale up access to essential diagnostics during crises?

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Power of Partnerships: Diagnostics at Warp Speed & Regulatory Reliance for Pandemic Diagnostics

PPPs enables rapid development, manufacturing, and distribution of diagnostics through shared risks and resources

- **Accelerator Diagnostics Pillar (ACT)**
  - Co-led by WHO, Foundation for Innovative New Diagnostics (FIND), Global Fund
  - Enabled rapid development, evaluation, and LMIC access to COVID-19 diagnostics
  - Delivered 180M+ tests with $1.8B mobilized
  - Partners: CHAI, PATH, UNICEF and industry (Abbott and SD Biosensor)
- **WHO–FIND Collaboration on EUL and Evaluation Network**
  - Enabled faster WHO listing of Covid-19 RDTs and NAATs using global lab network
- **WHO–GF–UNICEF Procurement Collaboration**
  - WHO provided normative guidance; Global Fund and UNICEF coordinated pooled procurement & supply logistics
  - Enabled large-scale deployment of WHO-recommended diagnostics in over 100 countries

WHO-led reliance mechanisms streamline regulatory decisions, especially where national capacity is limited, ensuring faster access to essential diagnostics during crises

WHO's Role in Regulatory Reliance for Diagnostics Access

- **Emergency Use Listing (EUL)**
  - Fast-track approval in **80+ countries;** Reduces duplication for quality-assured tests during emergencies
- **Prequalification (PQ) Program**
  - Ensures diagnostics quality and safety; supports regulatory reliance by NRAs and global procurement agencies
- **Regulatory Support & Regional Harmonization**
  - Joint reviews and capacity-building in LMICs

Agile regulation isn't about lowering standards—it's about smart efficiency. By leveraging WHO pathways, adapting for real-world use, and uniting through partnerships, we can ensure diagnostics reach everyone, everywhere, in time.

Acknowledgment

Dr Aytan Garayusifova, Consultant, WHO WPRO, DHS

"Without integrating diagnostics into UHC, 'health for all' remains rhetorical."
— Lancet Commission on Diagnostics