Laboratory Quality - the basis of diagnosis, care and treatment:

A key pillar for the elimination of mother to child transmission of HIV, Syphilis and Hepatitis B

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POLL

1. Where do the majority of testing errors occur:
   a. Pre-analytic area of testing
   b. Post-analytic area of testing
   c. Analytic area of testing
2. What percentage of medical error occurs in the diagnostic testing process?
   a. 10%
   b. 70%
   c. 50%
3. Which of the following causes the most testing error?
   a. Human
   b. Technical
   c. Organisational

POLL

4. Which of the following are impacts of testing errors?
   a. Delays in treatment
   b. Incorrect treatment
   c. Increased morbidity and mortality
   d. All of the above
5. What is required to ensure test accuracy and reliability?
   a. Implementation of laboratory standards to assure quality
   b. Hiring technologists who have a lot of experience.
   c. Using high tech equipment in the laboratory.
   d. All of the above.

POLL

6. Indicate if the following statements are **TRUE** or **FALSE**:
   a. Point of care tests are so simple that they do not require testing personnel to implement quality and safety standards. T F
   b. Laboratory requirements for certification of EMTCT are special requirements not required for other laboratory tests. T F
   c. External Quality Assessment (EQA) is required for all tests – whether done in the lab or at point of care. T F
   d. The window period no longer causes false negative results in rapid HIV testing due to improvements in technology. T F
   e. Use of the reverse algorithm for syphilis testing facilitates immediate treatment of pregnant women for syphilis T F
   f. Stockouts of key reagents and supplies continues to be a concern in provision of reliable testing for HIV, syphilis and Hep B. T F

Session Objectives

At the end of this session, participants will be able to:

i. Describe how testing errors can and do occur.

ii. Explain how accuracy and reliability of ALL testing requires implementation of specific quality and safety measures.

iii. Define key challenges to laboratory service quality and how they can be overcome for EMTCT and other disease programmes.

iv. Describe the critical importance of point-of-care testing to national HIV and syphilis control and prevention efforts and the need for rigorous quality oversight.

LAB QUALITY IMPACTS PEOPLE'S LIVES!

Nearly 70% of diagnostic errors occur during testing: ECRI STUDY (SEPT 2024)

https://www.beckershospitalreview.com/patient-safety-outcomes/nearly-70-of-diagnostic-errors-occur-during-testing-ecri.html?oly_enc_id=9929B1697990B5T

The main drivers of diagnostic errors in 2023 were issues with processing medical tests, referrals and communication, according to the Emergency Care Research Institute

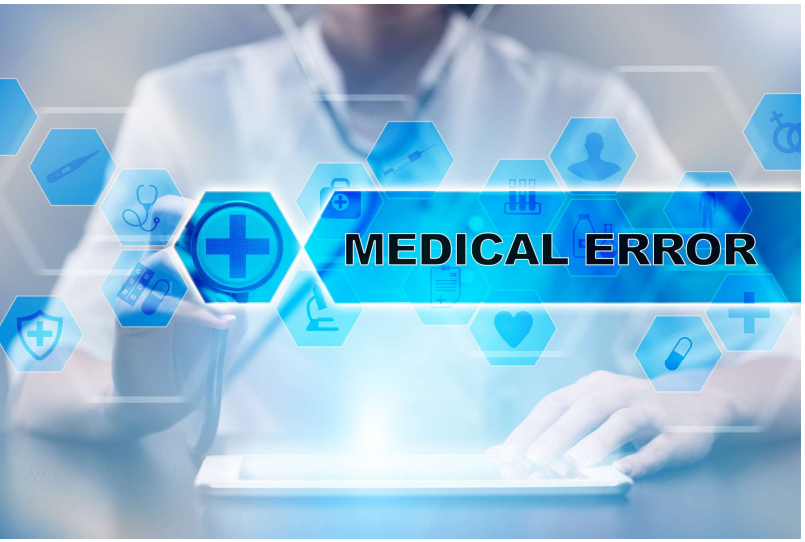
Nearly 7 in 10 errors occur during the testing process. The organization analyzed more than 3,000 patient safety adverse events and near-misses reported by healthcare workers.

Of those errors, **more than 23% were due to a technical or processing error,** "such as the misuse of testing equipment, a poorly processed specimen, or a clinician (tester) lacking the proper skill to conduct the test

Another 20% of testing errors were a result of mixed-up samples, mislabelled specimens, and tests performed on the wrong patient."

Twelve percent of diagnostic errors occurred in the monitoring and follow-up phase, and about nine percent happened during the referral and consultation phase, including miscommunication.

Lab Errors and their Impact



Blood test firm blamed for 'catalogue of disasters'. An NHS provider that won a £2bn contract to deliver blood-testing services is failing to deliver reliable results, according to medical professionals. Unreliable blood results, with erroneously high levels of potassium caused by processing delays, are a regular occurrence since the lab began the service. **BBC April 2025**

Patients bear brunt of failures by medical lab: The High Court of Jinja. Uganda awarded Shs190million in damages to Mr. John Wataka after he was incorrectly diagnosed with HIV and placed on ARVs for 7 years by the AIDS Support Organisation (Taso) despite being HIV negative. **MONITOR March 2026**

UKHSA publishes investigation findings following errors at the private Immensa lab: The laboratory was commissioned to provide additional testing capacity for NHS Test and Trace from 2 September 2021. UKHSA suspended testing at the laboratory on 12 October 2021 following reports of inaccurate results. UKHSA estimated that this error could have led to around 39,000 results (10% of samples tested) being incorrectly reported as negative when they should have been positive. **Press Release UKGOV 2022**

Lab Errors and their Impact

Charlotte attorney calls DNA lab errors 'incredibly troubling': Lab analyst uses positive control to test patient samples at Charlotte Crime Lab leading to errors in DNA test results used in rape and murder cases. **Queen City News 2024**

Error leaves 55,000 diabetes patients needing new tests: Errors by Trinity Biotech machines used to diagnose diabetes mean at least 55,000 people in England will need further blood tests, a BBC investigation has discovered. Some patients have been wrongly diagnosed with type 2 diabetes and even prescribed medication they don't need - and there could be more people affected, say NHS England. **BBC 2025**

Hospital Deaths Based on Faulty Test Results: Officials at St. Agnes Medical Center said tests of blood samples from 932 patients were improperly calculated. Some patients received incorrect doses of the anticoagulant warfarin between June 4 and July 25. Two patients who received treatment based on incorrect results died of intracranial hemorrhage. **CBS 2001**

Cause of Clinical Laboratory Errors

Cause of Errors n%	Pre-Analytic	Analytic	Post-Analytic	Total
Human	888 (86.1)	1 (0.1)	50 (4.9)	939 (91.1)
Technical	28 (2.7)	0 (0.0)	58 (5.6)	86 (8.3)
Organisational	4 (0.4)	0 (0.0)	2 (0.2)	6 (0.6)

The most common error subtypes were incorrect test ordering (48.2%) and specimen collection (34.6%)

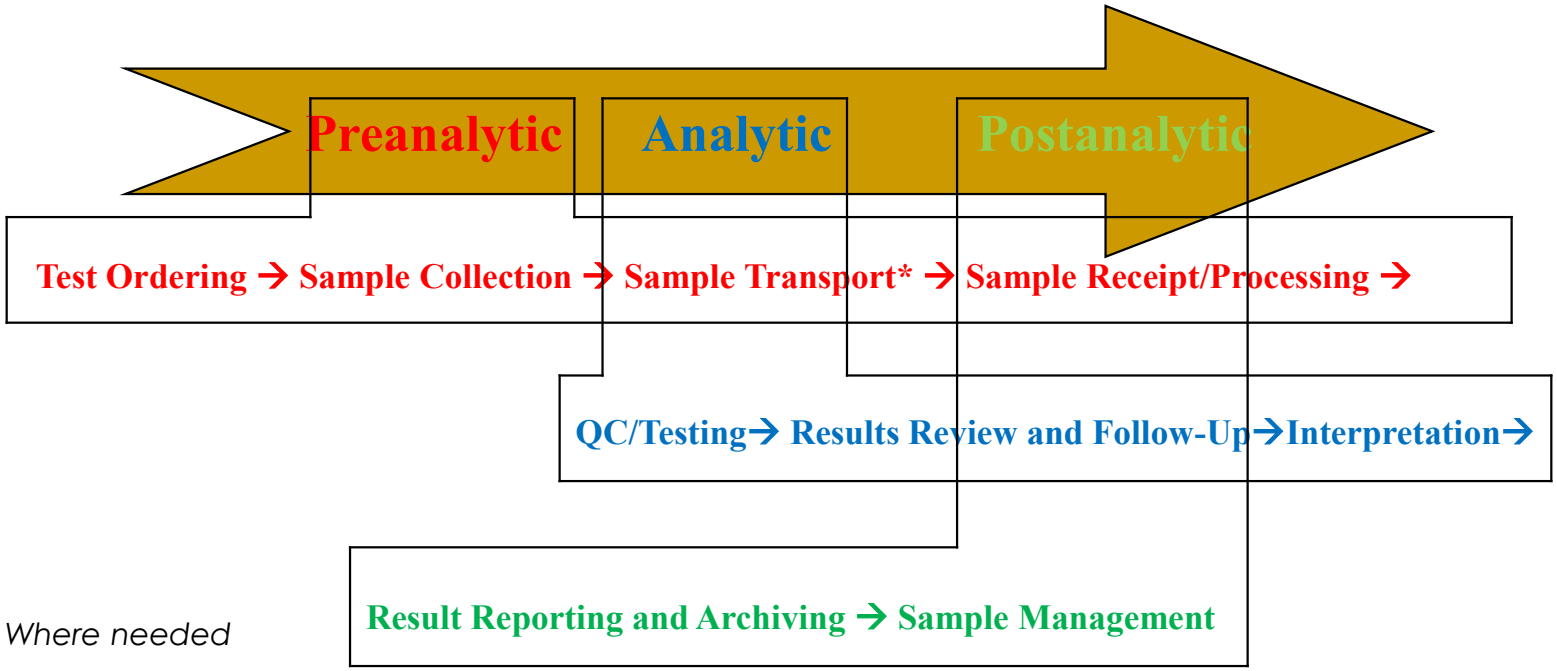
Diagnostic errors in clinical laboratory testing process: incidence and impacts on patient safety—a 3-year voluntary incident report analysis: Montri Saengpattrachai et al.

International Journal for Quality in Health Care, 2026, 38(2), https://academic.oup.com/intqhc/article/38/2/mzag038/8524329

15 March 2026

The Testing 'Path of Workflow' is a process

ref: CLSI GP26



* Where needed

Significant Potential for client harm… Pre-analytic

ALL TESTS (including rapid tests):

- poor sampling technique
- compromised or spoilt samples
- poor transportation process
- transcription errors
- inaccurate data management
- accurate results to wrong persons
- inaccurate results to the right persons
- ***wrong treatment***
- ***increased mortality or morbidity***
- ***negative social implication for client***

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Significant Potential for client harm… Analytic

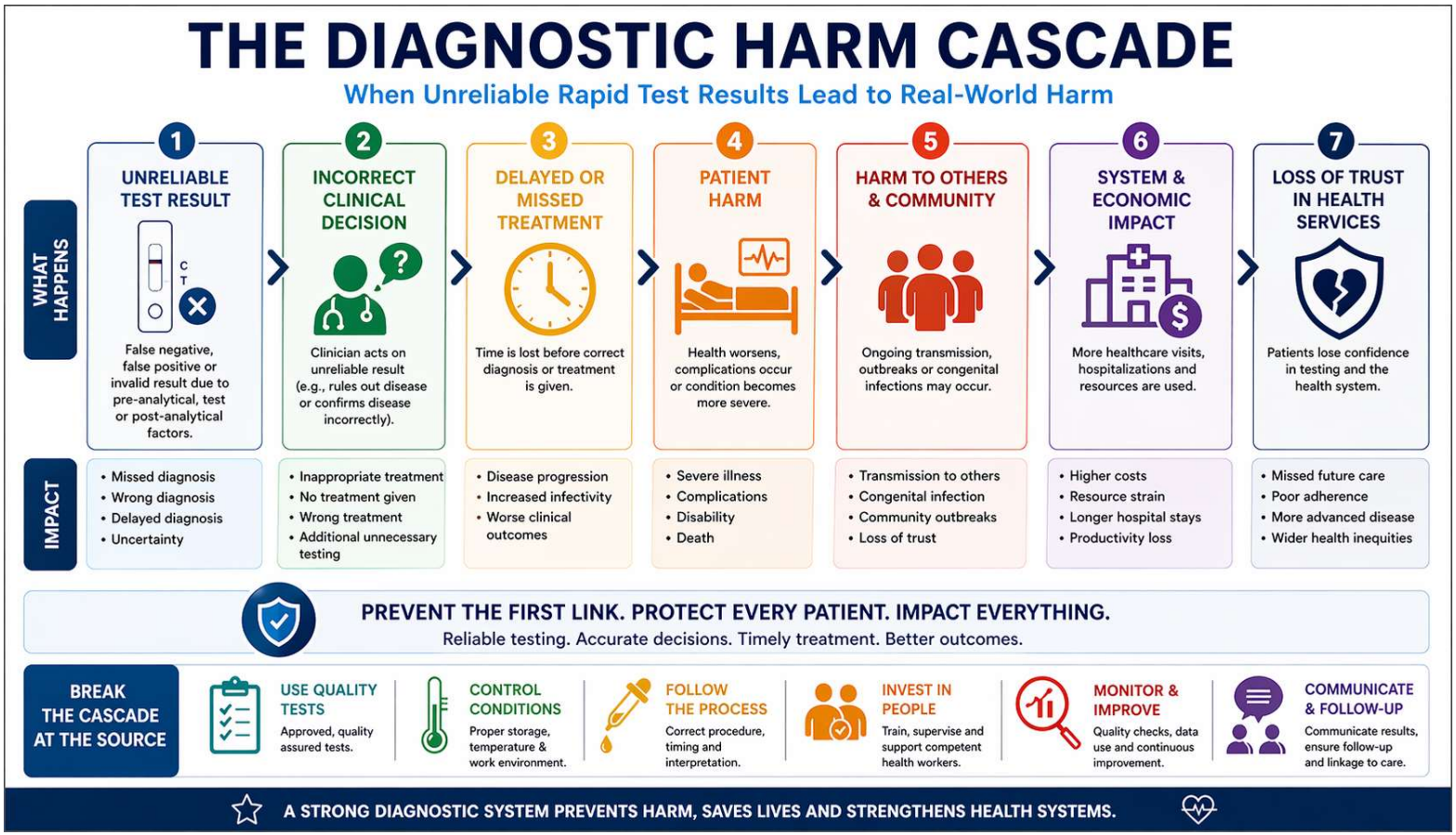
ALL TESTS (including rapid tests):

- Failure to **verify** test kits or test methods
- incorrect quality control
- poor technique (lack of competence)
- wrong methodology
- malfunctioning equipment
- expired reagents or spoilt reagents
- failure to participate in EQA programmes
- wrong result or wrong interpretation
- ***wrong treatment***
- ***increased mortality or morbidity***
- ***negative social implication for client***

Significant Potential for harm… Post-analytic

ALL TESTS (including rapid tests):

- lost reports
- mixed-up reports
- incorrect results reporting
- delayed results reporting
- lack of confidentiality
- poor record keeping
- poor data management
- ***client frustration***
- ***loss of trust***
- ***wrong treatment***
- ***increased mortality or morbidity***


THE DIAGNOSTIC HARM CASCADE
When Unreliable Rapid Test Results Lead to Real-World Harm
WHAT HAPPENS
IMPACT
1
UNRELIABLE TEST RESULT
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False negative, false positive or invalid result due to pre-analytical, test or post-analytical factors.
• Missed diagnosis
• Wrong diagnosis
• Delayed diagnosis
• Uncertainty
2
INCORRECT CLINICAL DECISION
Clinician acts on unreliable result (e.g., rules out disease or confirms disease incorrectly).
• Inappropriate treatment
• No treatment given
• Wrong treatment
• Additional unnecessary testing
3
DELAYED OR MISSED TREATMENT
Time is lost before correct diagnosis or treatment is given.
• Disease progression
• Increased infectivity
• Worse clinical outcomes
4
PATIENT HARM
Health worsens, complications occur or condition becomes more severe.
• Severe illness
• Complications
• Disability
• Death
5
HARM TO OTHERS & COMMUNITY
Ongoing transmission, outbreaks or congenital infections may occur.
• Transmission to others
• Congenital infection
• Community outbreaks
• Loss of trust
6
SYSTEM & ECONOMIC IMPACT
More healthcare visits, hospitalizations and resources are used.
• Higher costs
• Resource strain
• Longer hospital stays
• Productivity loss
7
LOSS OF TRUST IN HEALTH SERVICES
Patients lose confidence in testing and the health system.
• Missed future care
• Poor adherence
• More advanced disease
• Wider health inequities
PREVENT THE FIRST LINK. PROTECT EVERY PATIENT. IMPACT EVERYTHING.
Reliable testing. Accurate decisions. Timely treatment. Better outcomes.
BREAK THE CASCADE AT THE SOURCE
USE QUALITY TESTS
Approved, quality assured tests.
CONTROL CONDITIONS
Proper storage, temperature & work environment.
FOLLOW THE PROCESS
Correct procedure, timing and interpretation.
INVEST IN PEOPLE
Train, supervise and support competent health workers.
MONITOR & IMPROVE
Quality checks, data use and continuous improvement.
COMMUNICATE & FOLLOW-UP
Communicate results, ensure follow-up and linkage to care.
A STRONG DIAGNOSTIC SYSTEM PREVENTS HARM, SAVES LIVES AND STRENGTHENS HEALTH SYSTEMS.

HIV AND SYPHILIS RAPID TEST ALGORITHMS

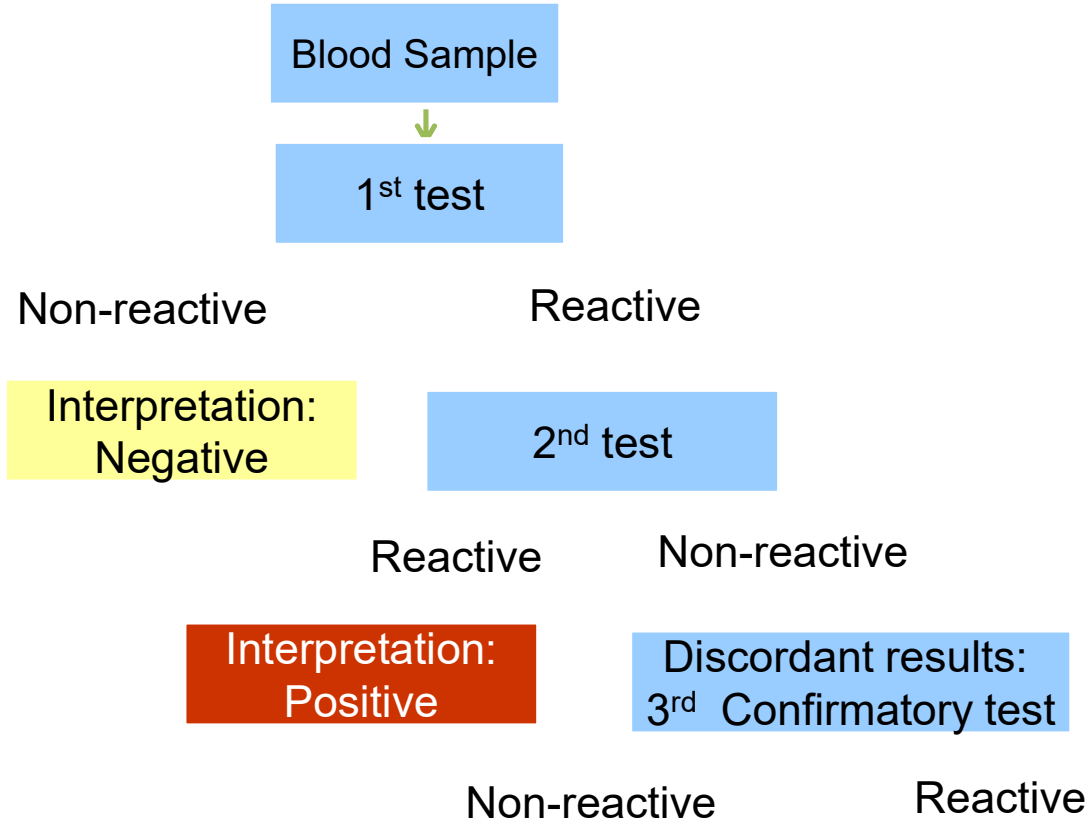
Testing Strategies & Algorithms

No single HIV test result is sufficient to diagnose & confirm HIV infection

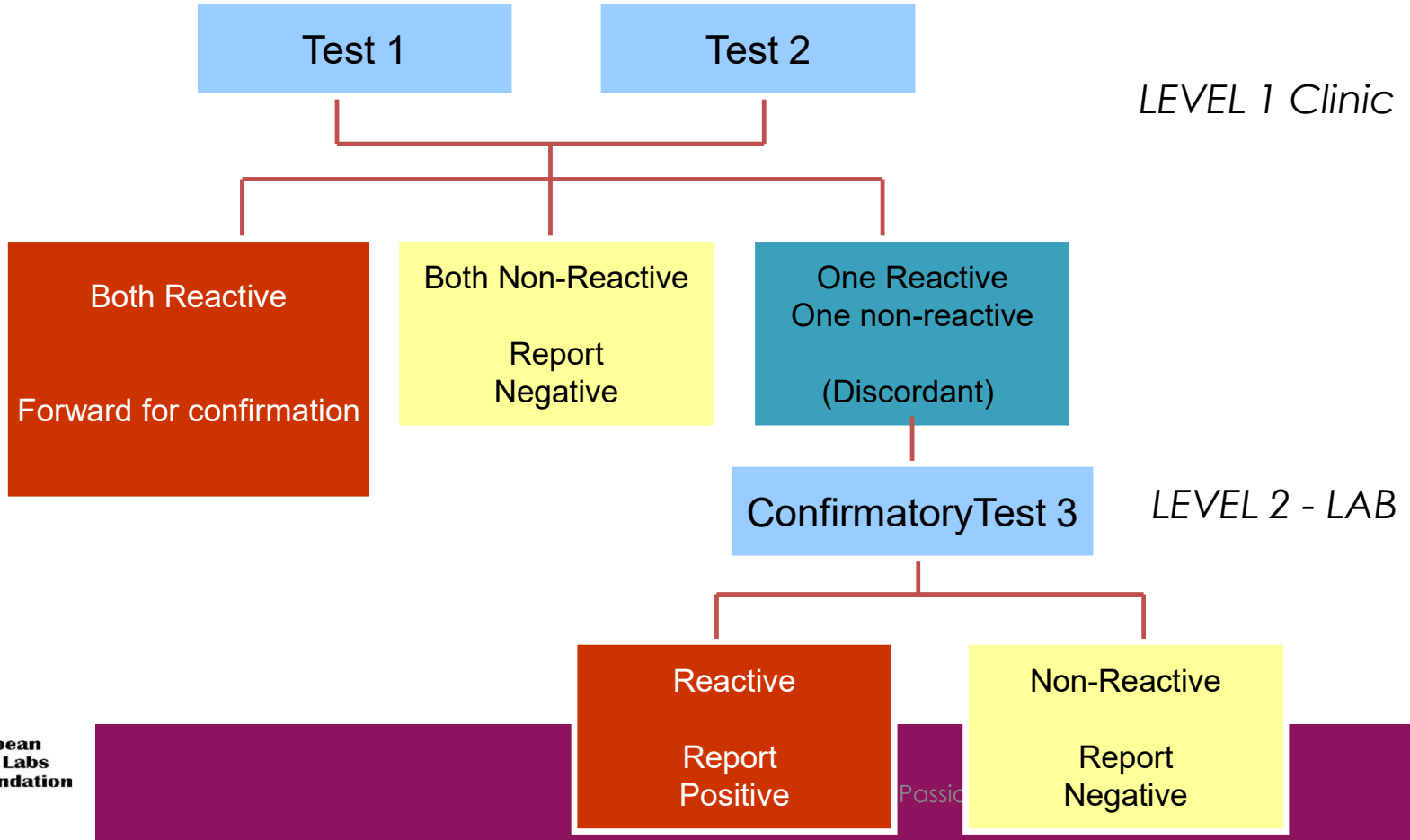
A combination of tests (an algorithm) is essential to confirm HIV infection

Algorithms must be validated for the particular environment and population (regionally nationally)

Serial Testing Algorithm



HIV Parallel Testing Algorithm



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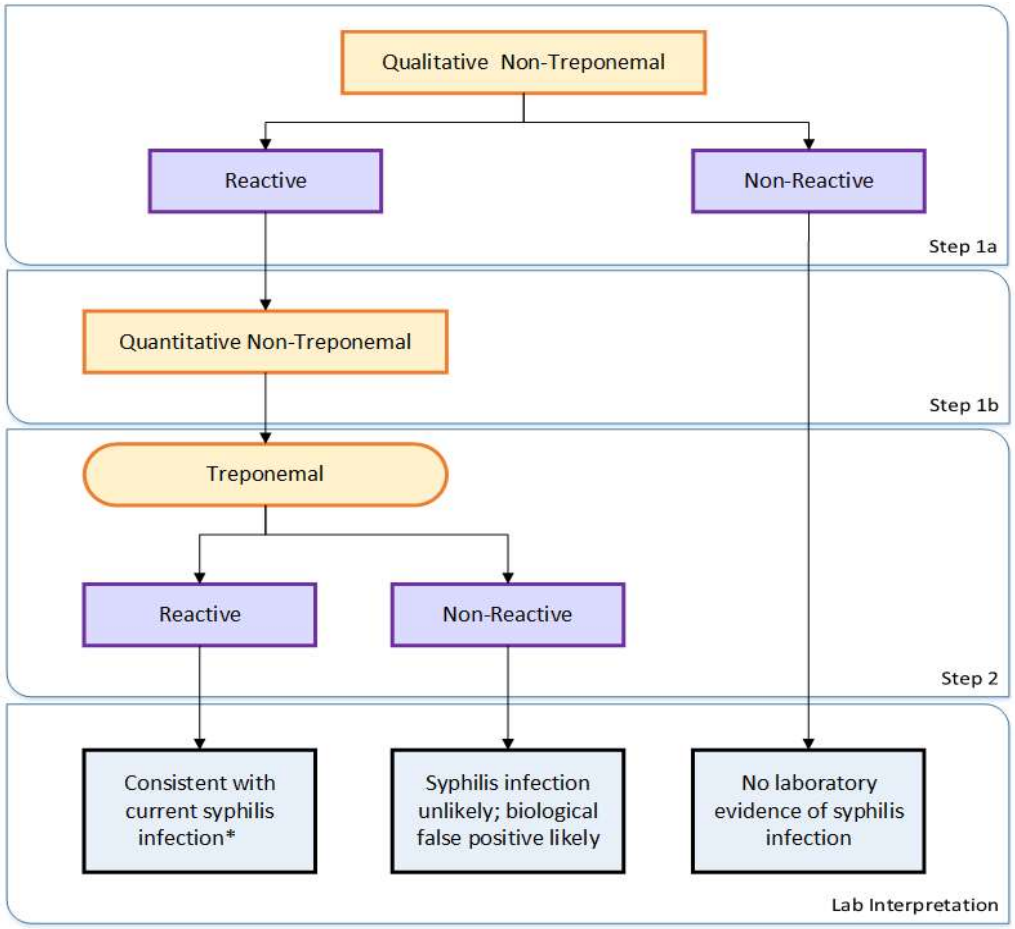
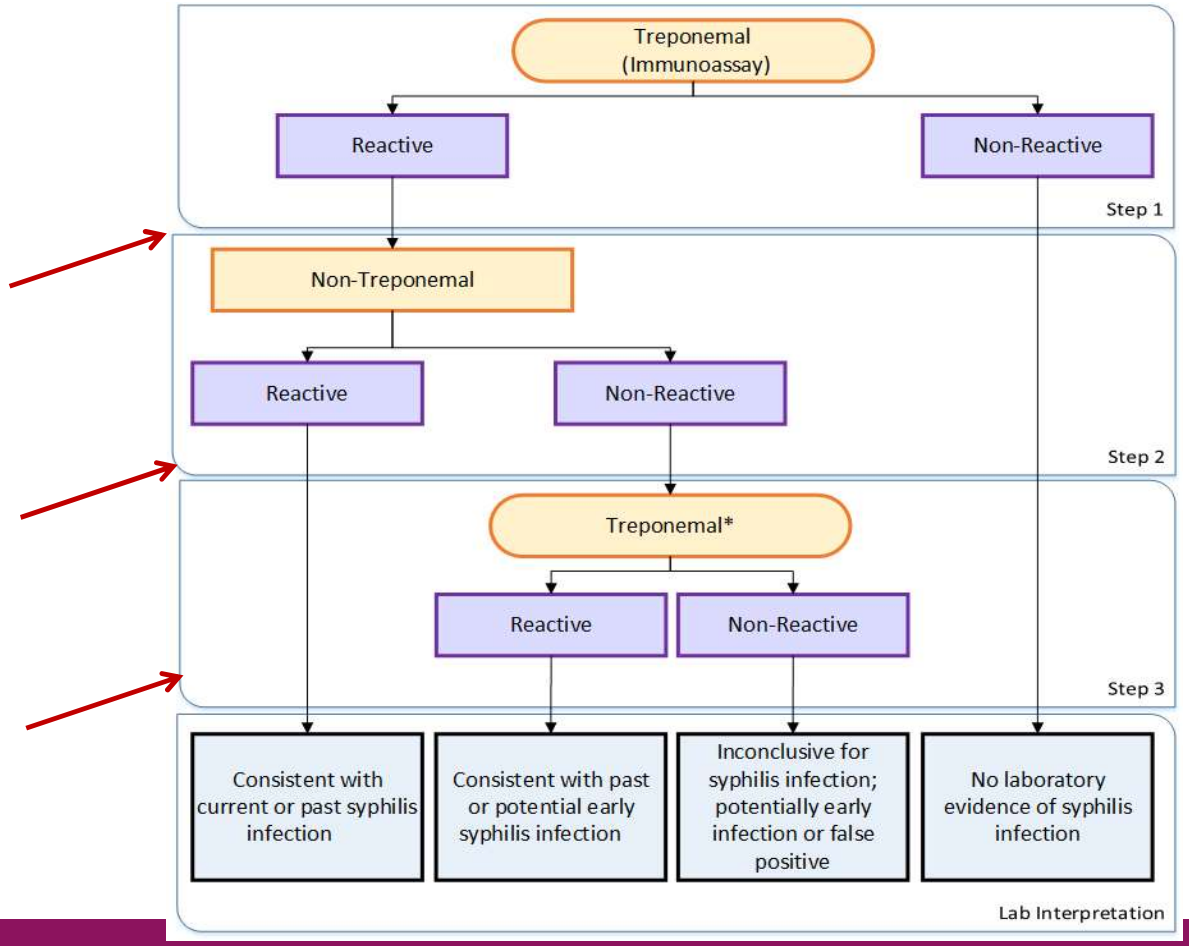
SYPHILIS TEST ALGORITHM:



SYPHILIS TEST ALGORITHM: REVERSE SEQUENCE



What Every Doctor Should Ask About Any Result….

Clinicians should ask some questions:

- Does result fit clinical picture?
- Was specimen adequate?
- Was timing of testing appropriate?
- Could a window period apply to this disease?
- Was testing QC acceptable?
- Was confirmatory testing needed & conducted?
- Could another condition interfere with this test result?
- What potential harm can occur from wrong results?

Key Requirements for EMTCT Certification of HIV & Syphilis and Hepatitis B - Laboratory Services

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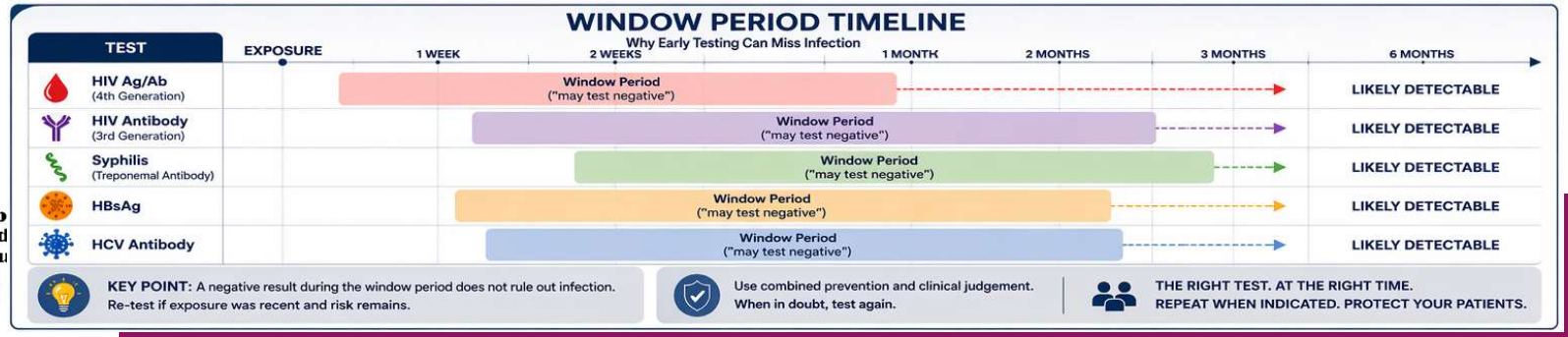
WHY DO TESTING SYSTEMS FAIL?



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Specific Testing Components

Testing conducted for mothers and infants:

- Serology testing test for mothers – HIV, syphilis and Hep B - according to verified algorithms
- Virological testing for mothers (HIV and Hep B Viral Load)
- HIV Virological testing for infants (EID)
- Syphilis testing for infants, including stillborn infants
- Evidence of EQA and other QMS measures for HIV, syphilis and HBV testing throughout different levels of testing services.

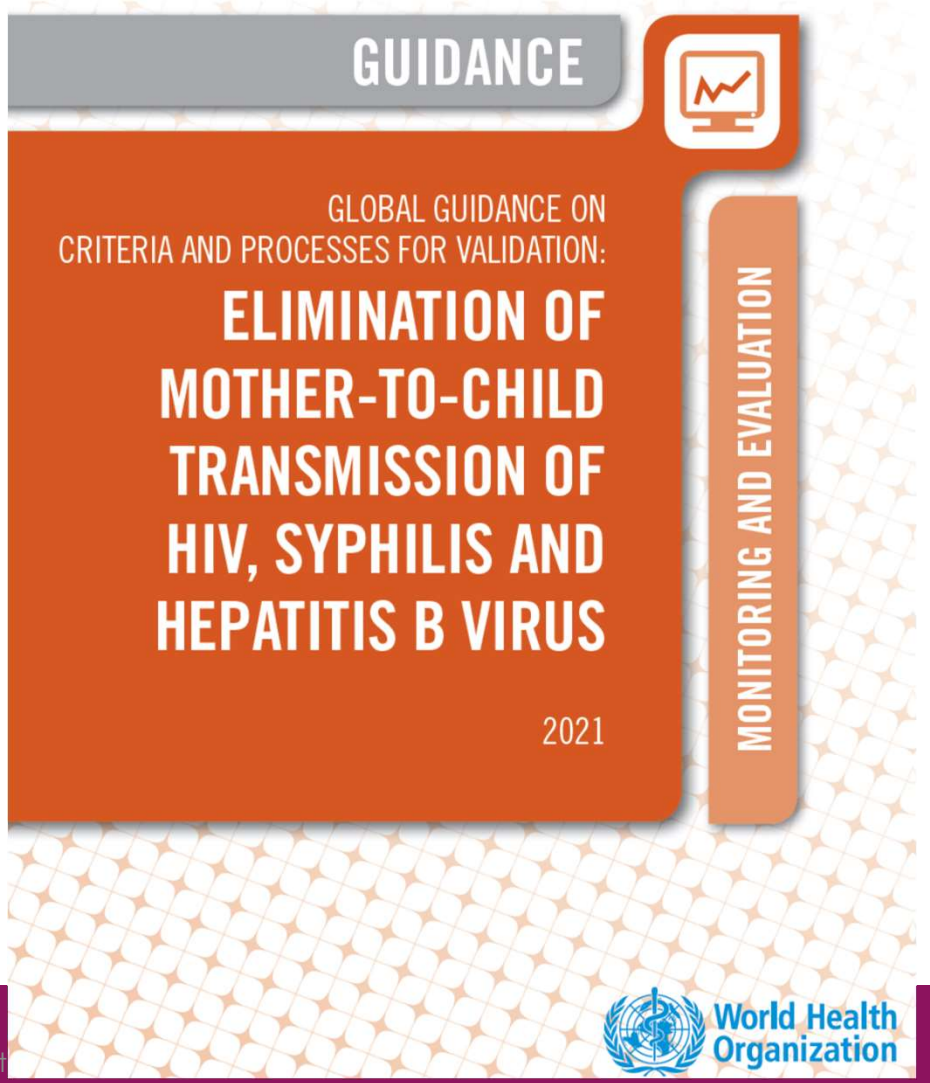
Laboratory Services – EMTCT Requirements

Draws on existing WHO and PAHO Guidance on:

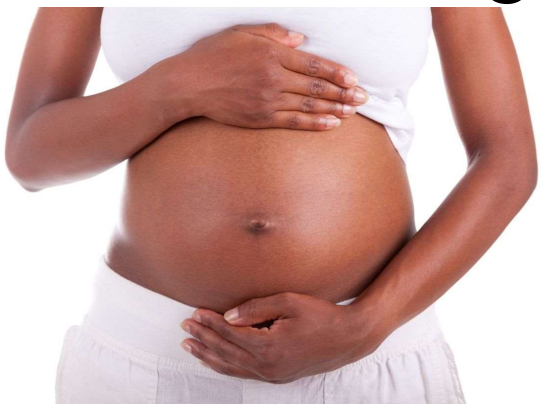
- Conduct of laboratory audits
- Laboratory Quality Improvement and Accreditation

And on the international Standard:

- **ISO 15189**: Medical Laboratories: Requirements for Quality and Competence



Laboratories contributing to surveillance and clinical monitoring



1. Have a **quality management system (QMS**) in place with sufficiently **supportive leadership and governance**
2. Ensure the **quality of test kits and procedures** – selection, procurement and storage according to international standards or regulatory equivalent
3. Ensure the quality of testing; **personnel performing tests have been trained and competency assessed** in accordance with **nationally recommended algorithms**
4. Have a laboratory quality assurance mechanism that is routinely and consistently applied and verified through participation in both **external and internal quality assurance programmes** for HIV, syphilis and HBV testing **at all levels**
5. Have a laboratory **data management system capable of providing data for surveillance and ensuring turnaround times** are monitored and maintained

Laboratory Quality

EMTCT validation

- Includes:
  - **External Quality Assessment** for the tests performed at **all levels**
  - **Implementation of basic quality requirements of ISO 15189** e.g. Caribbean Laboratory Quality Management Systems Stepwise Improvement Process (LQMS-SIP) or WHO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA)
  - **Review of laboratory and testing sites** – interviews, document and data review

1. Laboratory Quality Management

General organisation and functioning of the national HIV, syphilis and HBV laboratory programme:	Service delivery:	Supply chain management:
• Leadership and governance • National laboratory policy • Structure and co-ordination, management and supervision of the national lab network for EMTCT	• Organisation of services • Roles and responsibilities • QC of HIV, syphilis and HBV testing among pregnant women	• Availability of testing materials – stock-outs

2. Quality of Tests

Assessment of tests to evaluate whether they have acceptable operational characteristics as specified by organisations such as WHO, and relevant government and regulatory agencies.

National verified algorithms for HIV, syphilis and HBV in accordance with WHO or other international practices

Tests with appropriate quality characteristics suitable for maternal and child health services

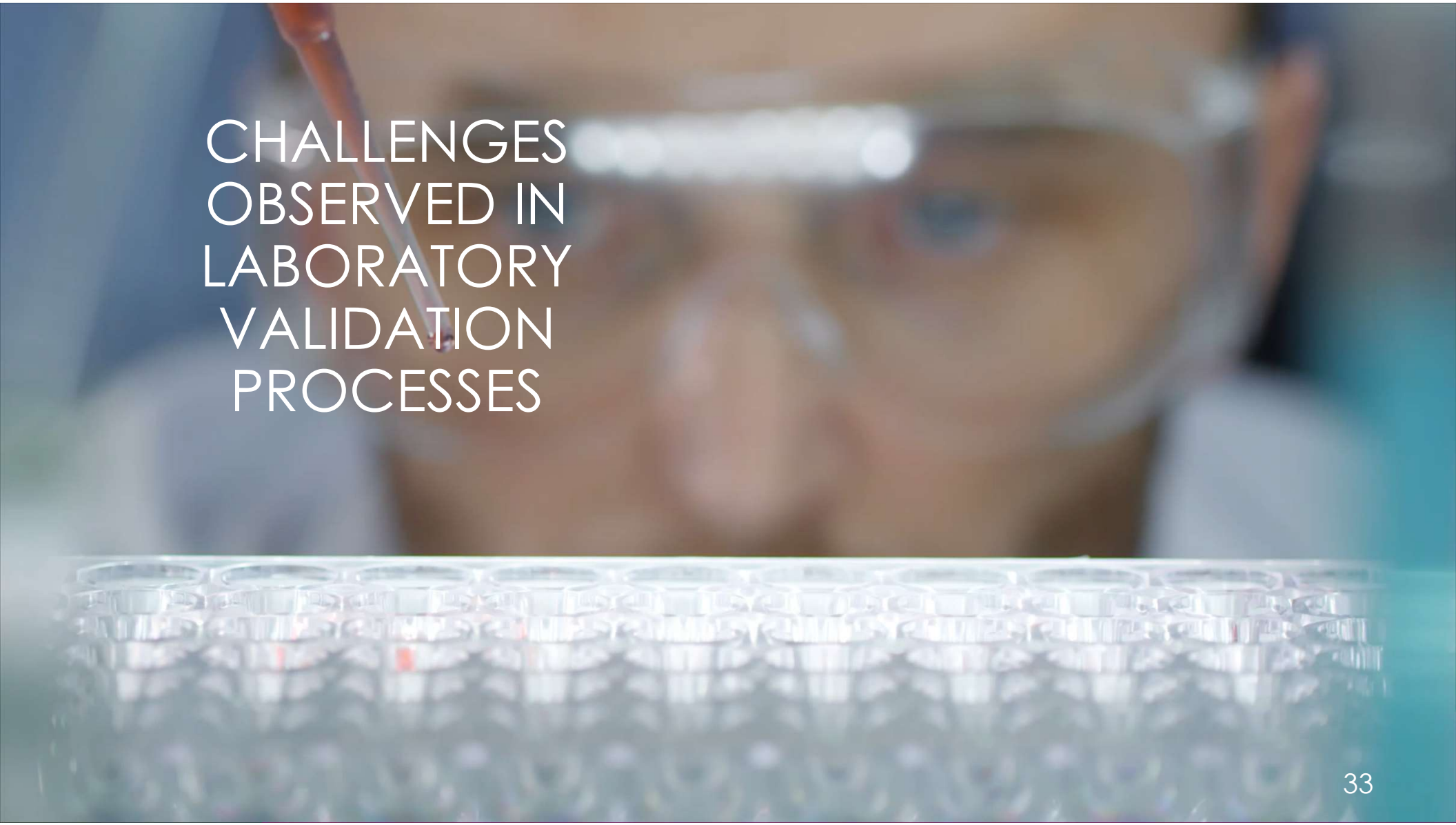
3. Quality of Testing

a. Assessment of staff competence through:

i. Professional licensure as technologists
ii. Appropriate training
iii. Competency assessment
iv. Staff proficiency in performing tests

4. Laboratory Data Management

a. Assessment of the laboratory's information management
   i. Functional **laboratory information system for recording** HIV, syphilis and HBV test results
   ii. Processes for the timely return of results to facilitate **timely treatment** of pregnant women and babies



CHALLENGES OBSERVED IN LABORATORY VALIDATION PROCESSES

COMMON CHALLENGES IN MEETING LABORATORY REQUIREMENTS

National laboratory policies in draft for many years	Insufficient QMS implementation	Unclear or incomplete algorithms and/or variable implementation of algorithms	POC tests not used appropriately e.g. used in labs instead of at maternity for mothers presenting in labour, at remote sites, etc.
Extended test turnaround times	Lack of evidence of EQA performance at **all levels of testing**	Inadequate supervision and monitoring of testing sites	Stockouts of key reagents and supplies

SOME KEY ISSUES

1. In-country and committee review requires experts in each area
2. Crossover among team members is key e.g. lab ⟷ programme ⟷ data, etc.
3. In-country reviews are extensive
   - Hybrid – virtual and in-country
4. Small countries or countries with low numbers of pregnant women – pooling of data
5. Strategies for larger countries or countries with high burden – stepwise process

CRITICAL COUNTRY SUCCESS FACTORS FOR EMTCT SUCCESS

1. Country commitment at all levels including political
2. Clear understanding of all technical requirements
3. Teamwork among all sectors – programme, data, lab, human rights
4. Consistent implementation and monitoring – data collection and analysis

COUNTRY GAINS BEYOND EMTCT

- EMTCT validation has motivated governments at the highest levels within the region resulting in **11 countries within the region achieving validation to date** (total 19 internationally)
- This high level of government engagement has **facilitated changes that had been delayed for many years** e.g.
  - Removal from the books of laws criminalizing sexual practices
  - Adoption of draft national lab policies by Cabinets in some countries
- **Health systems improvements** within countries that have achieved and maintained validation
- **Improved teamwork among health sector players** to achieve and maintain validation
- Introduction and use of electronic PAHO Perinatal Information System (SIP/SIP Plus) to **monitor key parameters and tests for pregnant women**

https://www.cmedlabsfoundation.com/