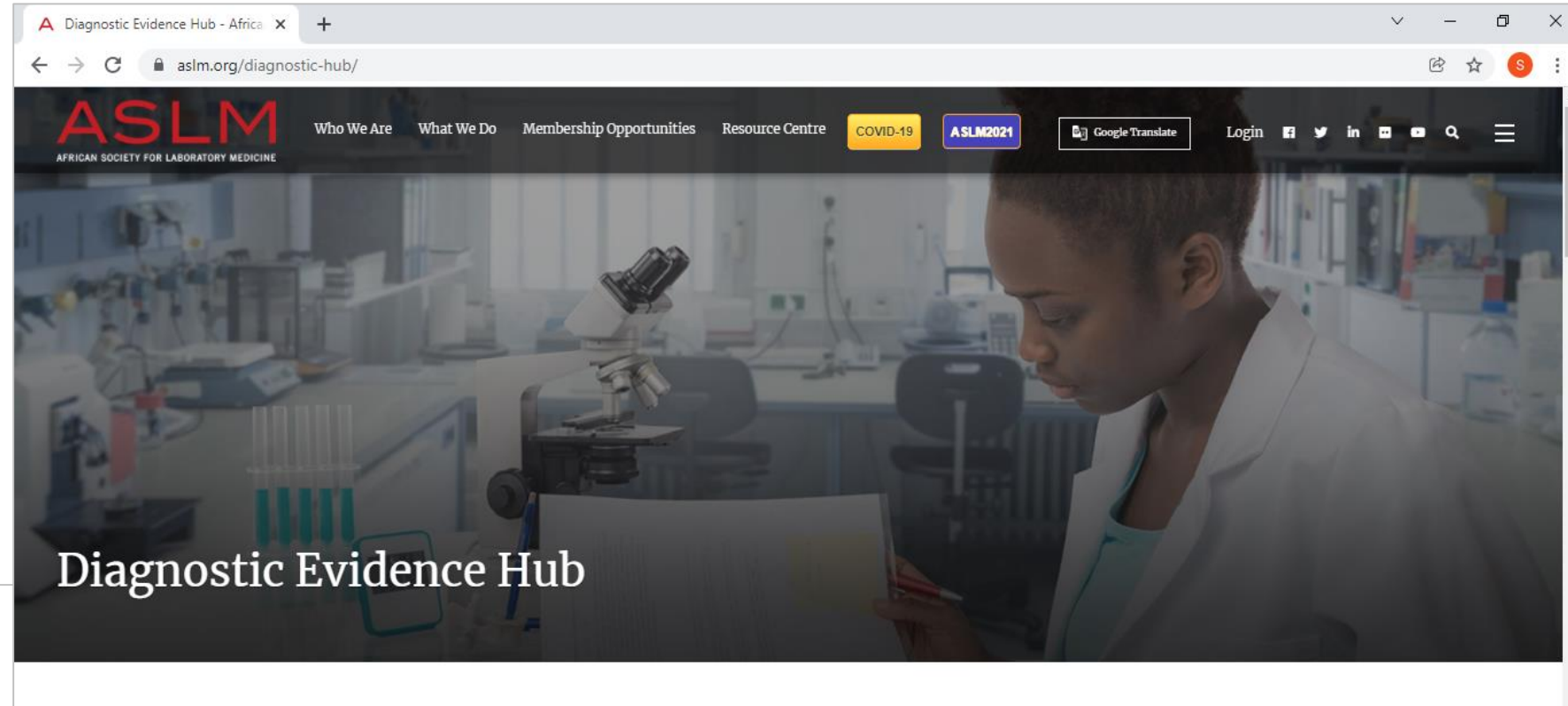




**The  
Diagnostic  
Evidence Hub:  
*Its role in  
Accelerating  
Uptake of  
Diagnostic  
Innovations***



Mashate Silver  
Program Manager, LabCoP, ASLM

**Special ECHO Session**

Dec 08, 2021

Oct 6, 2021, 06:35pm EDT | 1,197 views

## A Grim Diagnosis - Half The World's Population Has Limited Access To Diagnostics



**Madhukar Pai** Contributor 

Healthcare

*I write about global health, infectious diseases, and equity*

Follow

..... Tremendous effort and innovation has gone into Covid-19 testing. We now have rapid tests as well as home-based, self-tests for Covid-19, and have come up with easier and simpler ways of taking testing closer to people's homes and schools. Mobile testing sites, drive-through testing, and sample collection via community health workers, neighborhood pharmacies, schools and workplaces are all happening. **We need to do the same for many other areas in global health and 'democratize' access to testing.....**

Madhukar Pai

# Access to quality diagnostics

THE LANCET

THE LANCET COMMISSIONS | [ONLINE FIRST](#)

 The *Lancet* Commission on diagnostics: transforming access to diagnostics

[Kenneth A Fleming, FRCPATH](#) • [Prof Susan Horton, PhD](#)   • [Prof Michael L Wilson, MD](#) • [Prof Rifat Atun, FRCP](#) • [Prof Kristen DeStigter, MD](#) • [John Flanigan, MD](#) • et al. [Show all authors](#)

Published: October 6, 2021

47% of global population lack access to basic diagnostics for many common diseases

Gap greatest in primary care => **19%** in LMICs have access to the simplest diagnostic tests (other than for HIV or malaria)

- Easy access to diagnostics is far from guaranteed.
- Global commitments:
  - Universal health coverage (UHC)
  - Health-related Sustainable Development Goals
  - Global Health Security (IHR)

# In vitro diagnostic devices (IVD) registration process in Africa

- Highly variable registration process across the regions:
  - ✓ Technical documentation (dossier)
  - ✓ Samples
- Different regulations for registration, renewals and changes
- Import permit issues

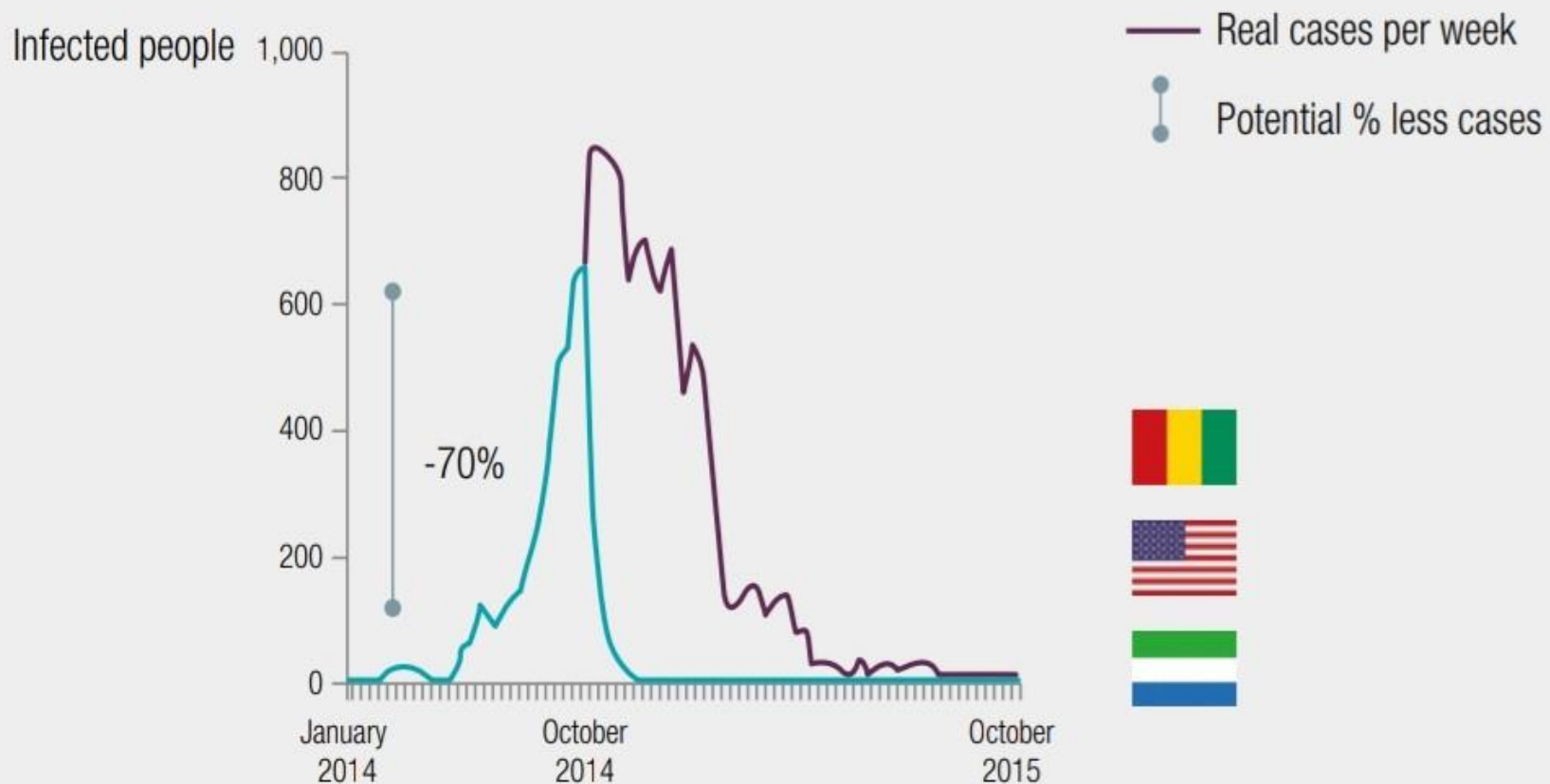
- Different lead-time, validity period and costs
- Informal/inaccessible registration regulation in some countries
- Limited human resources capacity/trained personnel



1. Inability to register all product ranges in each country
2. Inability to launch new products in all African countries at the same time
3. Prevent some countries to access to quality innovative and affordable IVD

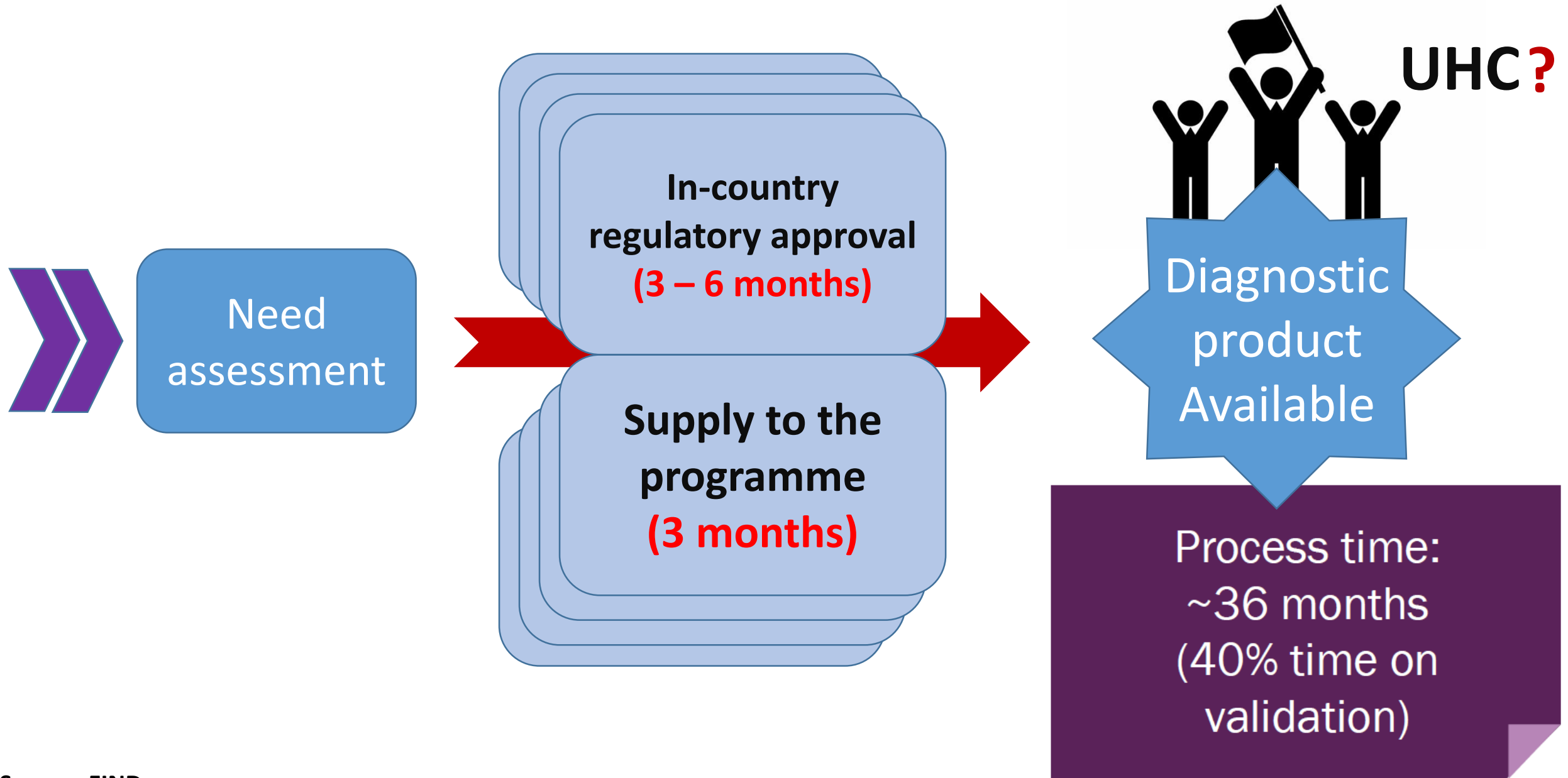
# Impact of early availability of diagnostics....

Case study: Potential impact of earlier availability of a rapid diagnostic test on the 2014–15 Ebola outbreak



Models suggest early diagnosis could have controlled 30–70% of cases, potentially saving thousands of lives and billions of dollars in the cost of response alone.

# 1. Technology introduction pathway



# Some repeat evaluations have not added value !

## The current status of TB-LAMP



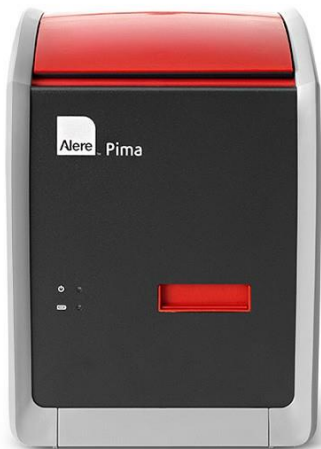
	Angola	Brazil	Cameroon	Colombia	DR Congo	Ethiopia	Ghana	Greece	Haiti	India	Indonesia	Iran	Ivory Coast	Kenya	Madagascar	Malawi	Mexico	Nigeria	Pakistan	Peru	Philippines	Senegal	Somalia	South Africa	Tanzania	Uganda	Vietnam	Zambia
Evaluation	Done	Done	Done	Ongoing	Ongoing	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done
Registration	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done
Inclusion in National Guideline	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done
Routine Implementation	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done	Done

● Done   
 ● Outstanding   
 ● Ongoing   
 ● Not applicable/needed   
 \* Private sector



Poor recognition & reliance leading to multiple, similar laboratory validation studies

## PIMA CD 4



Multiple > 20 Countries have conducted the evaluation of the PIMA point-of-care CD4+ count machines in various settings



# Enabling IVD registration process through harmonised regulation will improve access to new diagnostics

- Unified or convergent regulations/process across regions
- Formal, clear and established process
- Adequate human resources capacity/skilled personnel
- Predictable lead-time – short and timely
- Reasonable costs

## Regulation of IVDs in Africa



Regulations	Burundi	Kenya	Rwanda	Tanzania	Tanzania/ Zanzibar	Uganda	Ethiopia	Nigeria	South Africa
Legal framework	✓	✓	✓	✓	✓	-	✓	✓	✓
IVD regulated?	-	✓	-	✓	✓	-	✓	✓	✓
Premarket controls									
Adoption of GHTF classification	-	-	-	✓	✓	-	✓	In process	✓
Registration	-	+	-	✓	-	-	✓	✓	✓
Clinical performance	+	✓	-	✓	-	✓	✓	-	✓
Evaluation capacity				Limited		HIV only	Limited		
Manufacturing audit	-	-	-	-	-	-	-	-	-
Marketing controls									
Advertising control	✓	+	-	✓	-	✓	✓	✓	✓
Marketing controls	-	+	HIV, TB	✓	-	✓	✓	✓	✓
Postmarketing controls									
Surveillance	-	+	-	✓	-	-	-	-	✓
Accredited laboratories	-	✓	-	✓	-	✓	✓	-	✓
Device reporting	-	+	-	-	-	-	-	-	✓
Corrections/recall	-	+	-	-	-	-	-	-	✓

Abbreviations: GHTF, Global Harmonization Task Force; HIV, human immunodeficiency virus; IVD, in vitro diagnostics; TB, tuberculosis.

McNerney and Peeling Clin Infect Dis 2015;61(S3):S135-40



Africa Medical Devices Forum





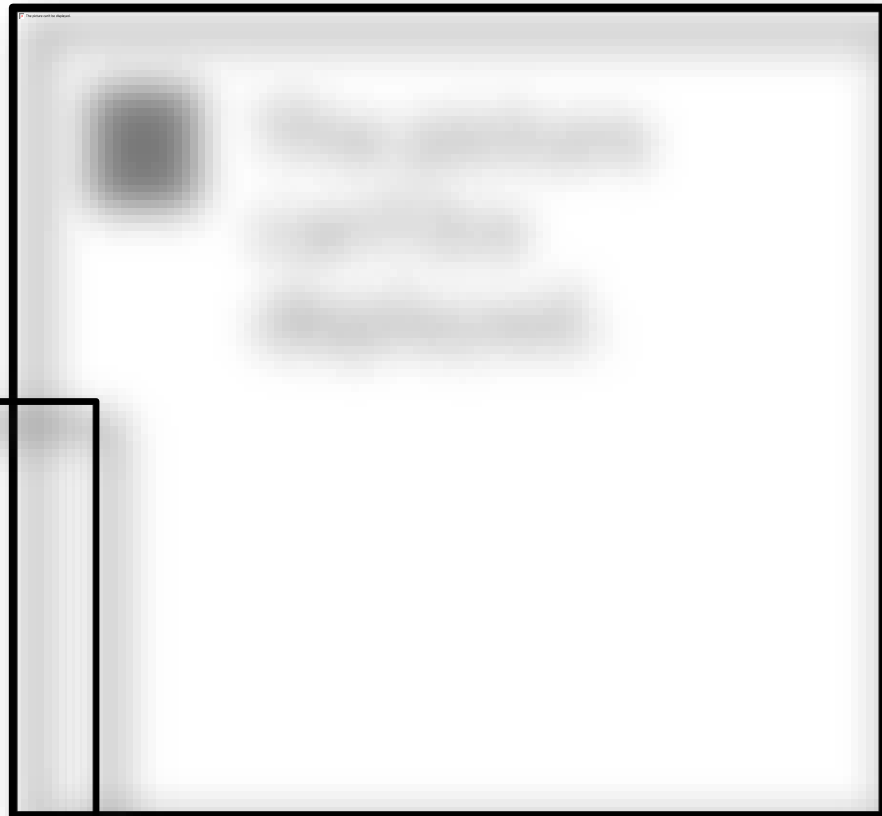
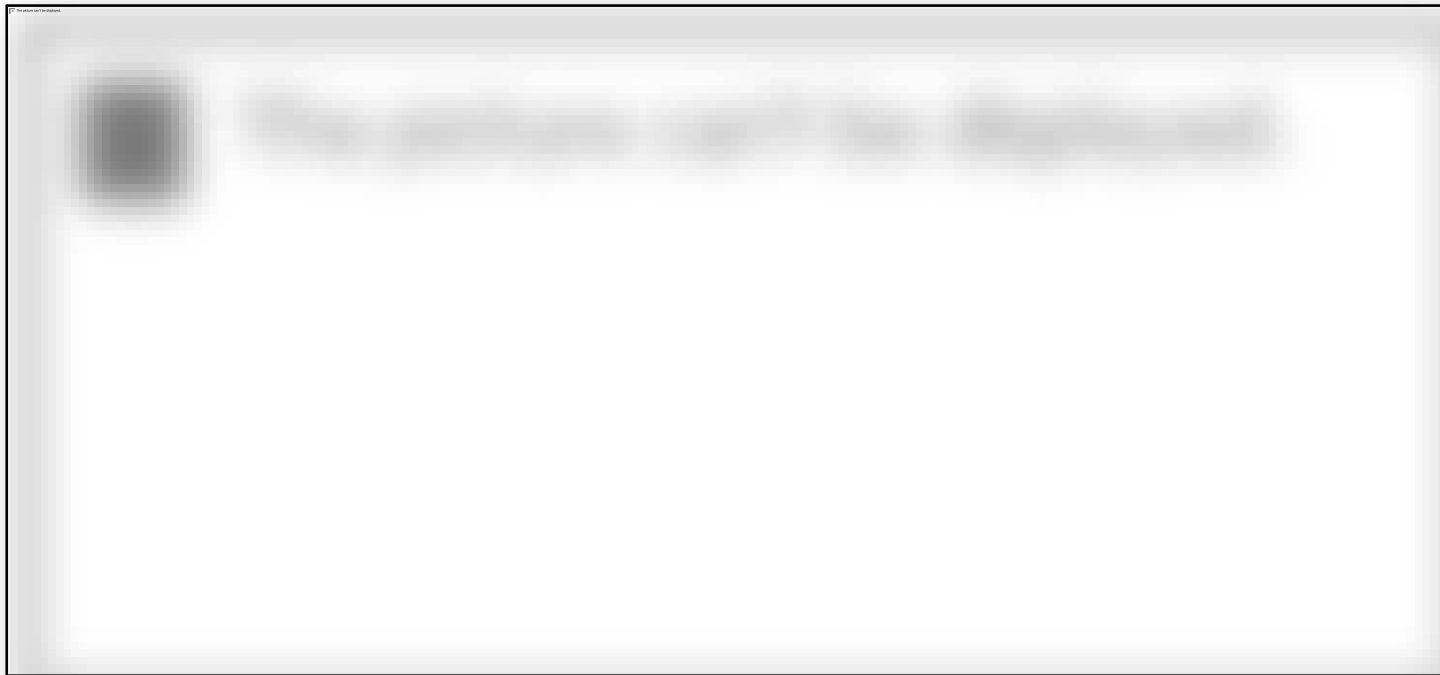
# Prequalification of IVDs and the Collaborative Registration Procedure



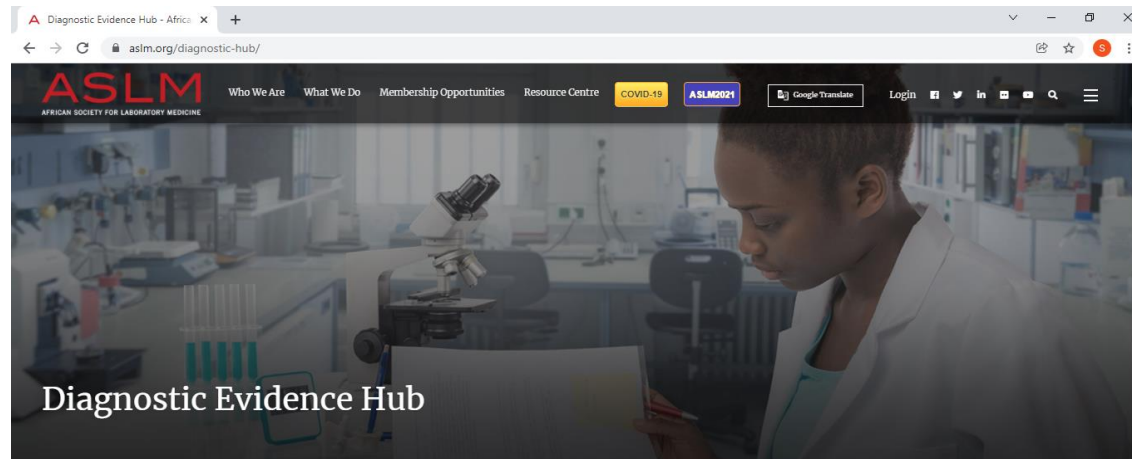
## In vitro Diagnostics assessment Team

Dr Susie Braniff

December 2021



Hosted on ASLM's website at  
<https://aslm.org/diagnostic-hub/>



## Current products:

- HIV -Already built
- TB
- Malaria } In development
- *More diseases to be considered in future*

- Aims to accelerate in-country registration and adoption new diagnostic innovations
- Knowledge **platform** for quick access to to published studies & field evalutaions for diagnostic innovations evaluation studies
- **Target audience:** National regulatory bodies, Policy Makers, Diagnostics experts, Lab. Scientists
- Access to consolidated regulatory and performance data for POC assays/new invitro diagnostic innovations
- Pooled data for **already performed field evaluations** at a one stop point
- Helps stakeholders reduce on time searching for new diagnostic innovations' performance characteristics
- Evaluation data presented at the hub are from published works, field based experiences
- Only data on for WHO PQ & independent re-known bodies is included



- ASLM and its Partners do not necessarily endorse any specific manufacturers
- **Only presents:** facts and data from WHO PQ, Independent bodies & published data sources/information

# Accessing and navigating the Diagnostic Evidence Hub

The screenshot shows the ASLM website with a navigation menu open. The menu items are: ASLM Academy, Diagnostic Evidence Hub (highlighted in red), Global Health Security, Integrated Diagnostics Consortium, LabCoP, LabMaP, MAAP, Outbreak Coverage, and PEPFAR. Below the menu are buttons for 'MEMBERSHIP OPPORTUNITIES' and 'EXPLORE OUR RESOURCES' (with 'SLIPTA' below it). The background features a '10 Years' anniversary logo and the text 'We are ASLM Working to advance the laboratory medicine profession and associated networks throughout Africa'. A 'COVID-19' button is visible in the top navigation bar. The bottom right corner includes the 'ASLM 2021' logo, 'ASLM2021 Website' link, and 'STRATEGIC SPONSORS' with logos for Beckman Coulter and Roche.

https://aslm.org/diagnostic-hub/



# Accessing and navigating the Diagnostic Evidence Hub

ASLM  
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Who We Are What We Do Membership Opportunities Resource Centre COVID-19 ASLM2021 Google Translate Login

## Diagnostic Evidence Hub

The Diagnostic Evidence Hub is a knowledge platform that provides national reference laboratories, national regulatory authorities, and diagnostics stakeholders with key information from published studies on the technical performance of new in vitro diagnostic products. It seeks to improve access to publicly available technical data in order to inform decision-making and support in-country registration and adoption of new, impactful, and quality-assured diagnostic products.

Regulatory decision making with regards to the quality, safety and performance of medical devices and in vitro diagnostics highly depends on expertise that is available within laboratories. Good reliance

# Accessing and navigating the Diagnostic Evidence Hub

The screenshot shows a web browser window with the following elements:

- Browser Tabs:** "Diagnostic Evidence Hub - Africa" and "Attention - Google Search".
- Address Bar:** "aslm.org/diagnostic-hub/"
- Navigation Bar:** Includes the ASLM logo, "Who We Are", "What We Do", "Membership Opportunities", "Resource Centre", "COVID-19" (highlighted in yellow), and "ASLM2021" (highlighted in blue). A hamburger menu icon is on the right.
- Main Content Area (Red Background):**
  - Section Header:** "New Diagnostic Products"
  - Text:** "Click on a category below to explore the available products."
  - Text:** "Only products that have been WHO prequalified have been included. Products that receive WHO prequalification in the future will be added to the Hub."
  - Text:** "ASLM and partners do not endorse any specific manufacturers. Products are listed alphabetically."
  - Buttons:** Three white buttons with rounded corners labeled "HIV", "TUBERCULOSIS", and "MALARIA".
- Secondary Content Area (Light Grey Background):**
  - Section Header:** "Evaluation and Verification Resources"
  - Text:** "Listed below are resources that can be used by laboratories for method verification and validation when a new diagnostic is introduced into a national program."
- Windows Taskbar:** Shows the search bar, taskbar icons for Edge, File Explorer, PowerPoint, Chrome, and Photos, along with system tray information: "25°C Mostly sunny", "10:57", and "08/12/2021".



# Accessing and navigating the Diagnostic Evidence Hub

The screenshot shows a web browser window with the URL `aslm.org/diagnostic-hub/`. The page features a red background with a molecular structure pattern. At the top, there is a navigation bar with the ASLM logo and a search bar. Below the navigation bar, the main content area is titled "New Diagnostic Products". A search filter "HIV" is applied, and the results are categorized into "POINT-OF-CARE EARLY INFANT DIAGNOSIS", "POINT-OF-CARE VIRAL LOAD", and "HIV SELF TESTING". Each category contains product cards with images and "VIEW PRODUCT" buttons. The "HIV SELF TESTING" category includes cards for INSTI HIV SELF TEST, MYLAN HIV SELF TEST, ORAQUICK HIV SELF-TEST, and SURE CHECK HIV SELF TEST. At the bottom of the page, there is a section for "Evaluation and Verification Resources". The Windows taskbar is visible at the bottom of the screen, showing the time as 10:58 on 08/12/2021.

Diagnostic Evidence Hub - Africa x Attention - Google Search x +

aslm.org/diagnostic-hub/

**New Diagnostic Products**

Click on a category below to explore the available products.

Only products that have been WHO prequalified have been included. Products that receive WHO prequalification in the future will be added to the Hub.

ASLM and partners do not endorse any specific manufacturers. Products are listed alphabetically.

HIV

POINT-OF-CARE EARLY INFANT DIAGNOSIS

POINT-OF-CARE VIRAL LOAD

HIV SELF TESTING

M - PIMA HIV - 1/2 DETECT  
VIEW PRODUCT

XPERT HIV-1 QUAL  
VIEW PRODUCT

M - PIMA HIV - 1/2 VIRAL LOAD  
VIEW PRODUCT

XPERT HIV-1 VIRAL LOAD  
VIEW PRODUCT

INSTI HIV SELF TEST  
VIEW PRODUCT

MYLAN HIV SELF TEST  
VIEW PRODUCT

ORAQUICK HIV SELF-TEST  
VIEW PRODUCT

SURE CHECK HIV SELF TEST  
VIEW PRODUCT

Evaluation and Verification Resources

Type here to search

25°C Mostly sunny 10:58 08/12/2021

# Accessing and navigating the Diagnostic Evidence Hub

**Xpert HIV-1 Qual** is a qualitative in vitro diagnostic test designed to detect Human Immunodeficiency Virus Type 1 (HIV-1) total nucleic acids using human whole blood (WB) and dried blood spot (DBS) specimens from individuals suspected of HIV-1 infection.

**Manufacturer:** Cepheid AB (Sunnyvale, CA, United States)

**Instrument Compatibility:** GeneXpert Dx, GeneXpert Infinity-48s and GeneXpert Infinity-80

**Detects:** HIV-1

**Quality Standards:** WHO PQ; CE marked

**WHO PQ Number:** PQ Dx 0259-070-00

**WHO Listing Date:** 13 June 2016

One systematic review has been published ([Agutu et al 2019](#)) which includes data from five studies that have assessed the performance of Xpert HIV-1 Qual Assay as compared with current reference standards. The assay performed well across the studies with high sensitivities (range: 93.3-100%) and high specificities (range: 99.5-100%).

[VIEW INTENDED USE](#)   [SUMMARISED RESULTS FROM WHO PREQUALIFICATION](#)

## Diagnostic Product Data

View a preview of the data for this product below or click the following button to view the full data summaries.

[CLICK TO SEE FULL DATA](#)

### Data Summaries Sheet

Author(s) ▲	Publication year ▲	Publication type ▲	Type of study ▲
Bwana P, et al	2019	Journal article	Field evaluation

11:35  
08/12/2021

# Accessing and navigating the Diagnostic Evidence Hun


The screenshot shows a web browser window with the ASLM Diagnostic Evidence Hub page. The browser tabs include 'Diagnostic Evidence Hub - Africa' and 'Attention - Google Search'. The address bar shows 'aslm.org/diagnostic-hub/'. The website header features the ASLM logo and navigation links: 'Who We Are', 'What We Do', 'Membership Opportunities', 'Resource Centre', 'COVID-19', and 'ASLM2021'. The main content area is titled 'Evaluation and Verification Resources' and includes a paragraph: 'Listed below are resources that can be used by laboratories for method verification and validation when a new diagnostic is introduced into a national program.' Below this are two columns. The left column, titled 'Verification', includes an icon of laboratory glassware and text: 'Verification, intended for assays used without modification, is conducted as part of good laboratory practice, fulfilling requirements of internal quality standards to confirm with evidence that manufacturer performance claims have been met. Calculations are based on experimental data, often using very minimal numbers of samples between 10 to 20.' The right column, titled 'Validation', includes an icon of a laboratory instrument and text: 'Validation, a more complex process, is required for modified or "in-house" tests. Validation is necessary if a standard method has been modified or is used outside its intended scope. Similar to verification, tests are validated according to clinical test purpose and impact of the result on the clinical decision. Technical specifications to be evaluated (e.g., error rate, allowable specificity and sensitivity) are selected accordingly.'

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Who We Are | What We Do | Membership Opportunities | Resource Centre | COVID-19 | ASLM2021

## Evaluation and Verification Resources

Listed below are resources that can be used by laboratories for method verification and validation when a new diagnostic is introduced into a national program.



**Verification, intended for assays used without modification, is conducted as part of good laboratory practice,** fulfilling requirements of internal quality standards to confirm with evidence that manufacturer performance claims have been met. Calculations are based on experimental data, often using very minimal numbers of samples between 10 to 20.



**Validation, a more complex process, is required for modified or "in-house" tests.** Validation is necessary if a standard method has been modified or is used outside its intended scope. Similar to verification, tests are validated according to clinical test purpose and impact of the result on the clinical decision. Technical specifications to be evaluated (e.g., error rate, allowable specificity and sensitivity) are selected accordingly.

Windows taskbar: Type here to search | 25°C Mostly sunny | 10:57 08/12/2021



## Other Useful Resources

**WHO PQ REGULATION AND PREQUALIFICATION (RPQ)**  
Facilitates access to safe, reliable, and appropriate in vitro diagnostics (IVDs) and laboratory services in an equitable manner, with a focus on IVDs for priority diseases and their suitability for use in resource-limited settings

**AFRICA MEDICAL DEVICES FORUM (AMDF)**  
A technical committee under the African Medicines Regulatory Harmonisation (AMRH) initiative, AMDF focuses on building effective regulatory networks for IVDs and medical devices

**INTERNATIONAL MEDICAL DEVICE REGULATORY FORUM**  
Discusses future directions in medical device regulatory harmonisation and works to accelerate international medical device regulatory harmonisation and convergence

**INTERNATIONAL DIAGNOSTICS CENTER**  
Facilitates the development, evaluation, and implementation of accessible, quality assured IVDs for global health through information sharing and advocacy

**ASLM RESOURCE CENTER**  
Additional resources posted on ASLM's website resource center

# **ASLM is considering expanding the Diagnostics Evidence Hub and is interested in feedback from stakeholders**

- What challenges are countries still facing when trying to introduce a new diagnostic product?
- Which aspects of the Diagnostic Evidence Hub are most helpful in addressing these challenges?
- How can the Diagnostics Evidence Hub be expanded to better support stakeholders to rapidly introduce new diagnostics?
  - Including additional types of HIV diagnostics e.g. dual HIV/syphilis RDTs?
  - Including diagnostics for other diseases e.g. TB?
  - Including evidence and tools for implementation and scale up of new diagnostics?



## Partner Acknowledgment

With support from the U.S. President's Emergency Plan for AIDS Relief, through the African Society for Laboratory Medicine, Catholic Relief Services and Clinton Health Access Initiative



**Thank you...**