

# ASLM

AFRICAN SOCIETY FOR LABORATORY MEDICINE

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA

## **Addressing the data gap to facilitate the regulation and uptake of IVD**

### **The ASLM perspective**

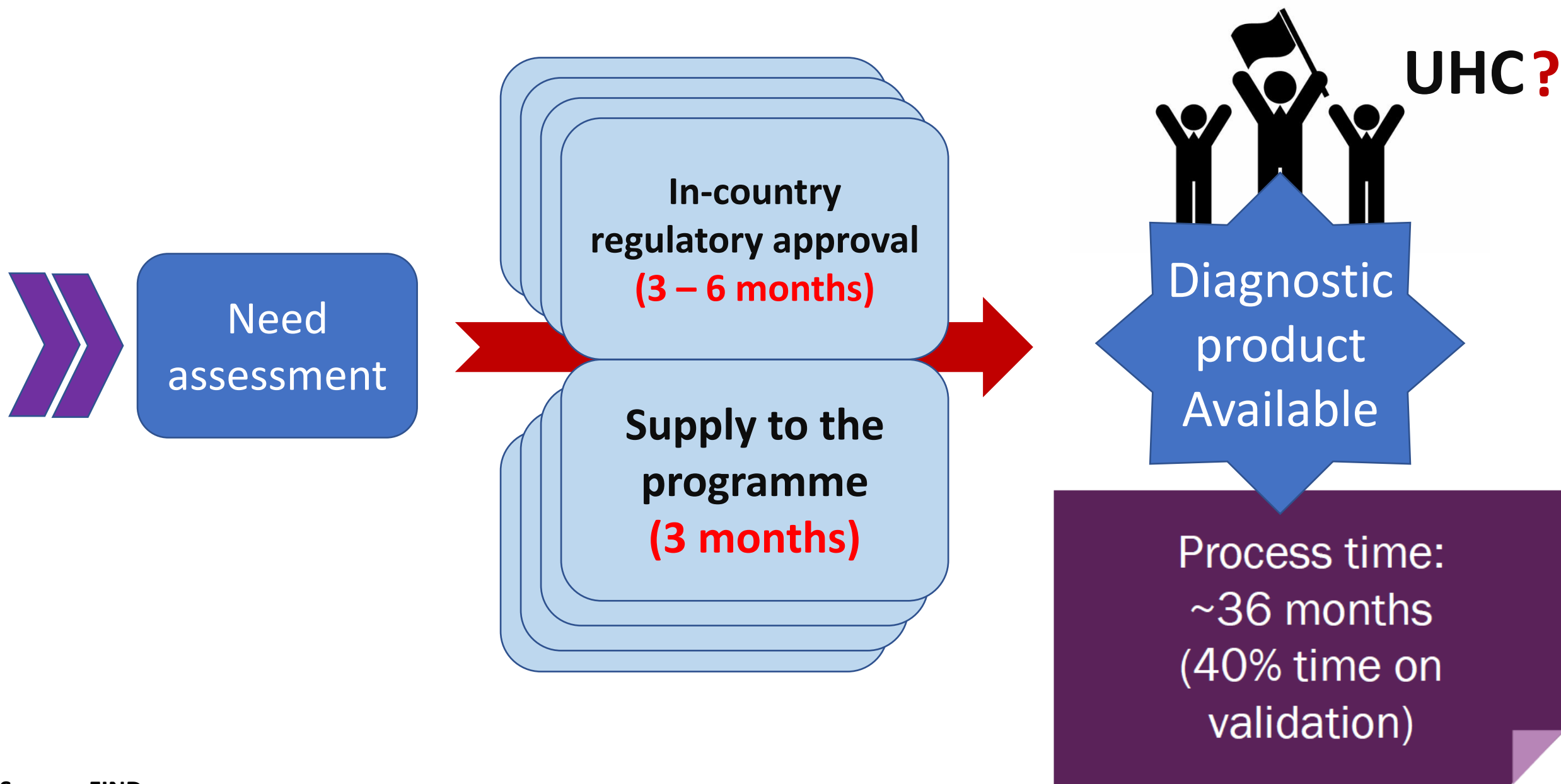
Anafi Mataka  
ASLM

*End-to-end diagnostics roundtable : IAS 2022 24 Feb 22*

# Registration and regulatory approval of diagnostics in LMICs

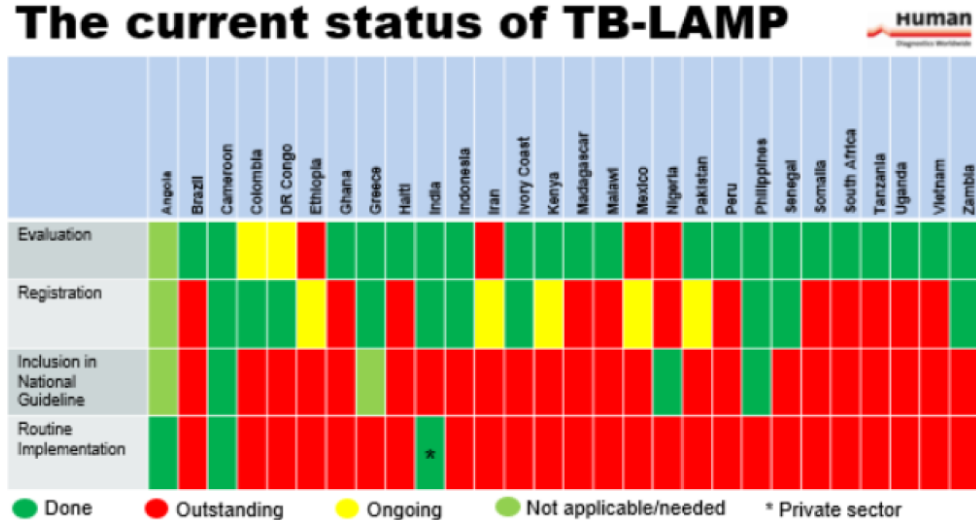
- Lengthy and complex registration processes that delay (sometimes up to years) and compromise access to quality-assured in vitro diagnostics (IVDs).
- Lack of uniform registration processes across regions
  - variable documentation requirements
  - lack of information, limited human resources in most countries' NRAs, prohibitive costs, and long lead times to registrations.
- Early availability of diagnostics is key

# 1. Technology introduction pathway



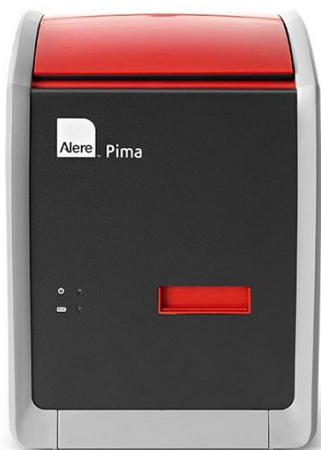
# Some repeat evaluations have not added value !

## The current status of TB-LAMP



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

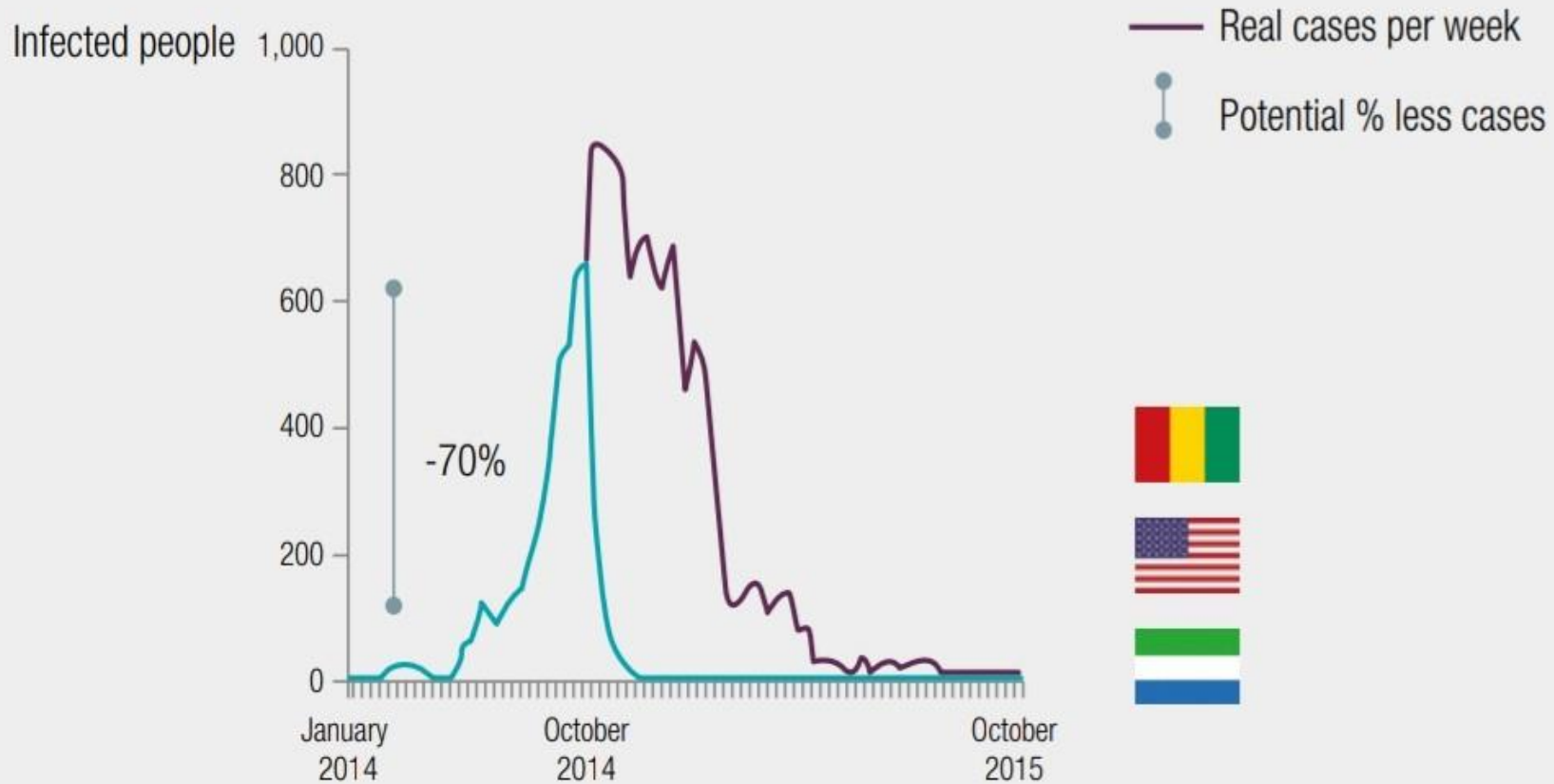
## PIMA CD 4



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

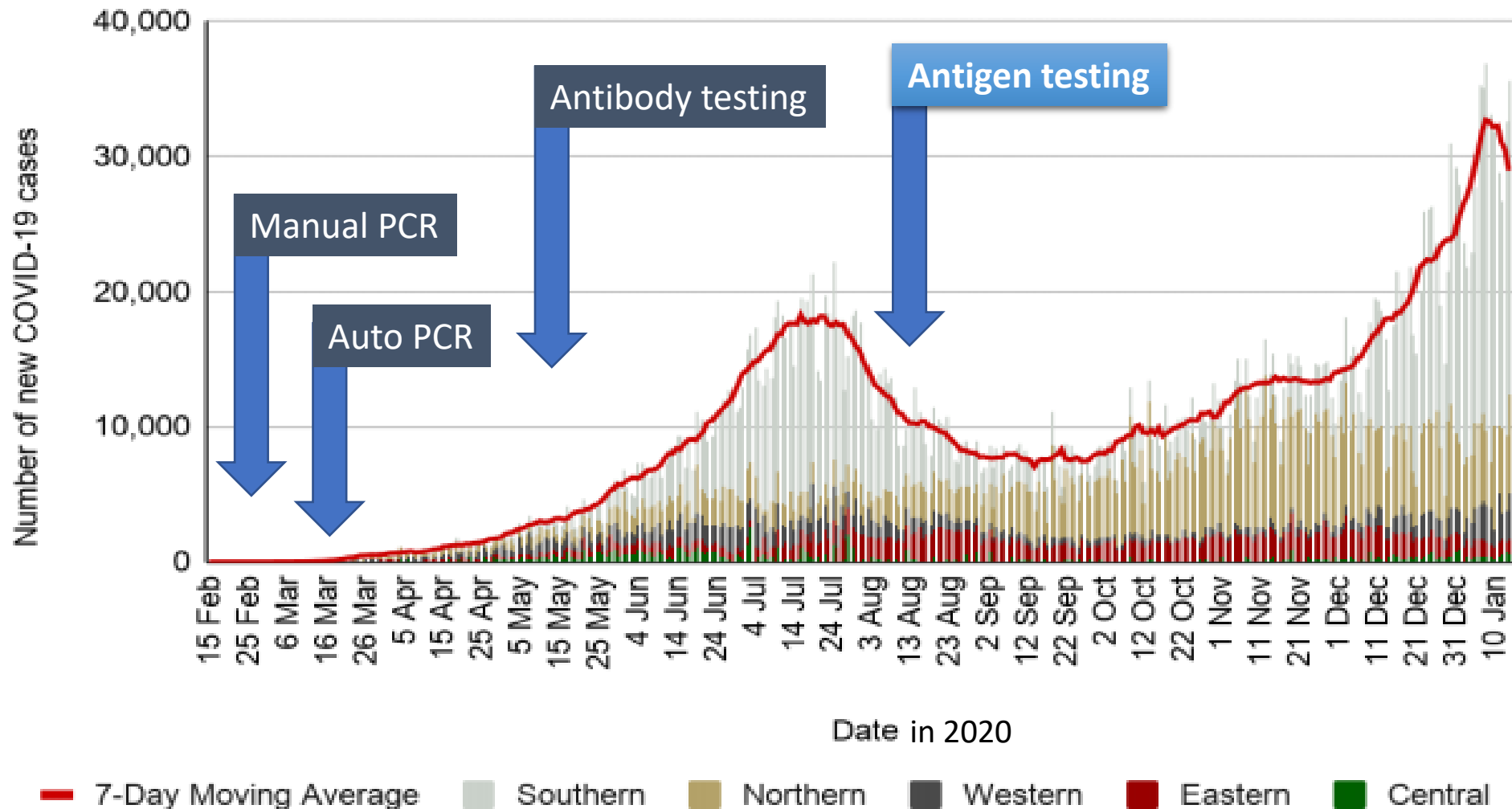
# Impact of early availability of diagnostics....

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.

# COVID-19: an epidemic of new tests

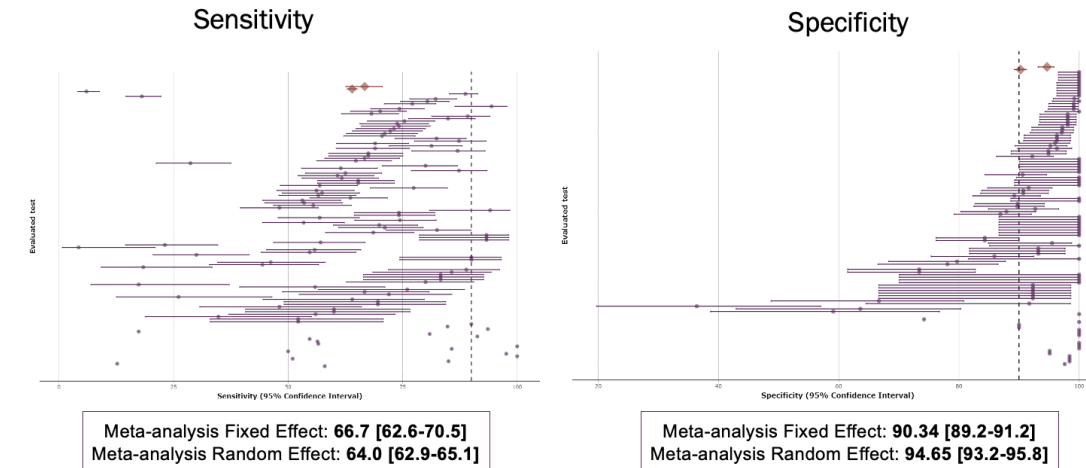


# Swift performance evaluation and validation of COVID -19 tests have been critical

- By February 2021, FIND had produced useful sets of data to inform the regulatory approval and uptake of COVID-19 testing.
- But usually, country lack access to relevant information on test performance for many diseases.



What do we know about performance? (3) FIND Data Aggregation: overall sensitivity is poor



<https://finddx.shinyapps.io/COVID19DxData/>

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ASLM diagnostic  
evidence hub

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

TUBERCULOSIS

MALARIA

Data Summaries Sheet   Performance Data Graph   Error/Failure Rate Graph

Author(s) ▲	Publication year ▲	Publication type ▲	Type of study ▲	Country ▲	Study period ▲	Intervention (assay) ▲	Comparator (assay) ▲	Sample Type ▲
Avidor B, et al	2017	Journal article	Laboratory evaluation	Israel	nr/nd	Cepheid GeneXpert HIV-1 Viral Load (Quant)	Roche CAP/CTM HIV-1 V2.0	Plasma



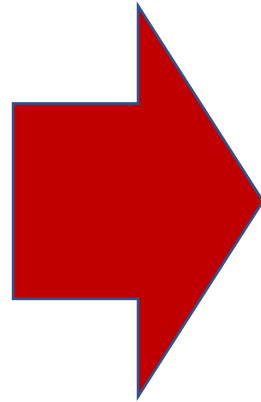
# Increasing the scope, relevance and user friendliness of the diagnostic hub: how?

- Shape the interface to the challenges that countries face the most when introducing a new diagnostic product
  - Including evidence and tools for implementation and scale up of new diagnostics?
- Increase the accessibility of the interface
  - Making sure decision makers (National public health laboratories responsible for evaluations ) and National regulatory authorities are continuously updated of the hub
  - Distinguishable subpage on the ASLM website under “what we do”
  - Evidence presented in downloadable table format for easy comparability of various studies
- Include data for more tests beyond HIV
  - What are the priority diseases, technologies and tests relevant to our countries?
  - Can we link up with the effort to define Essential Diagnostic Lists?



Other critical data gaps limiting  
diagnostic implementation

What are the priority diseases relevant to the epidemiology of various African settings, which are currently overlooked by national regulatory/uptake processes?

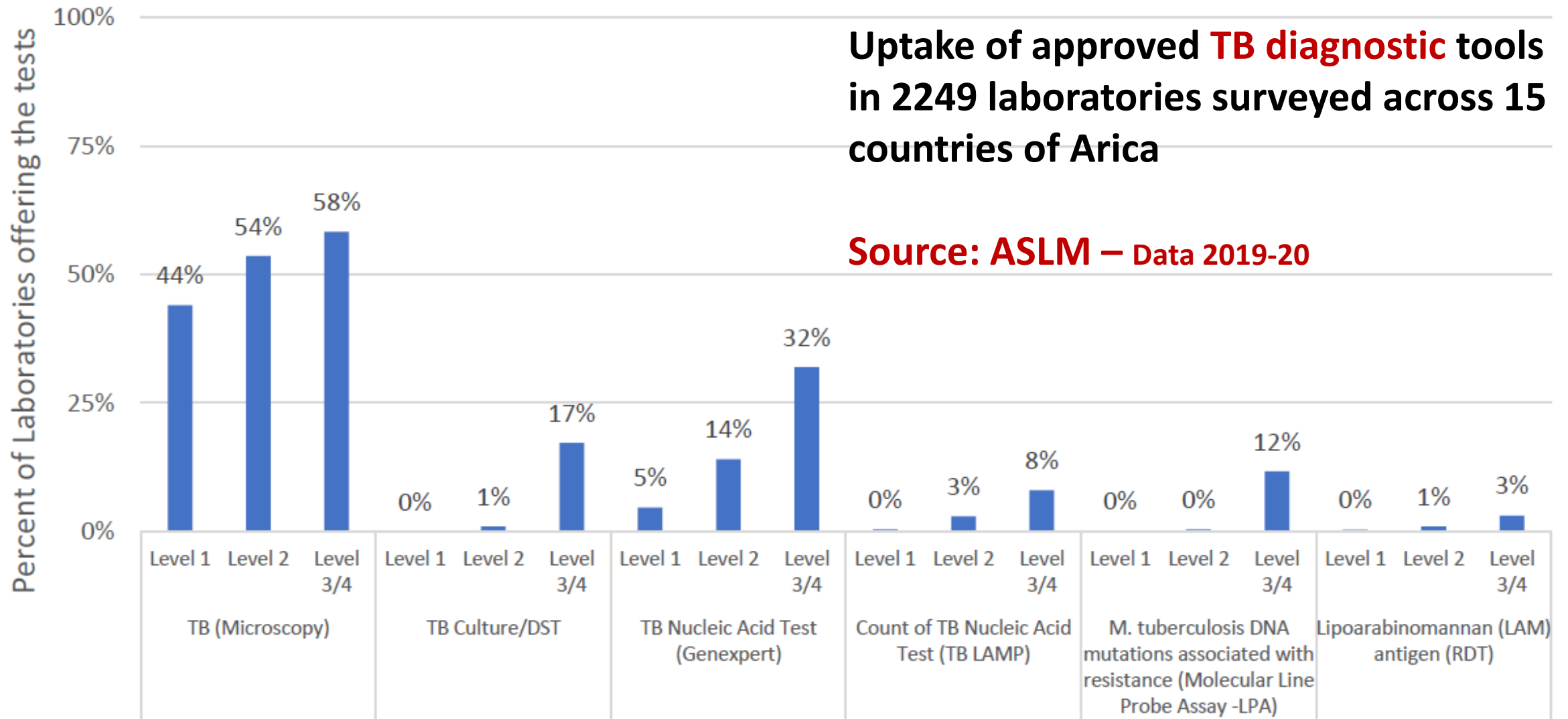


**10 of 38 countries of Africa** surveyed by ASLM define prioritized testing nationally and across diseases.

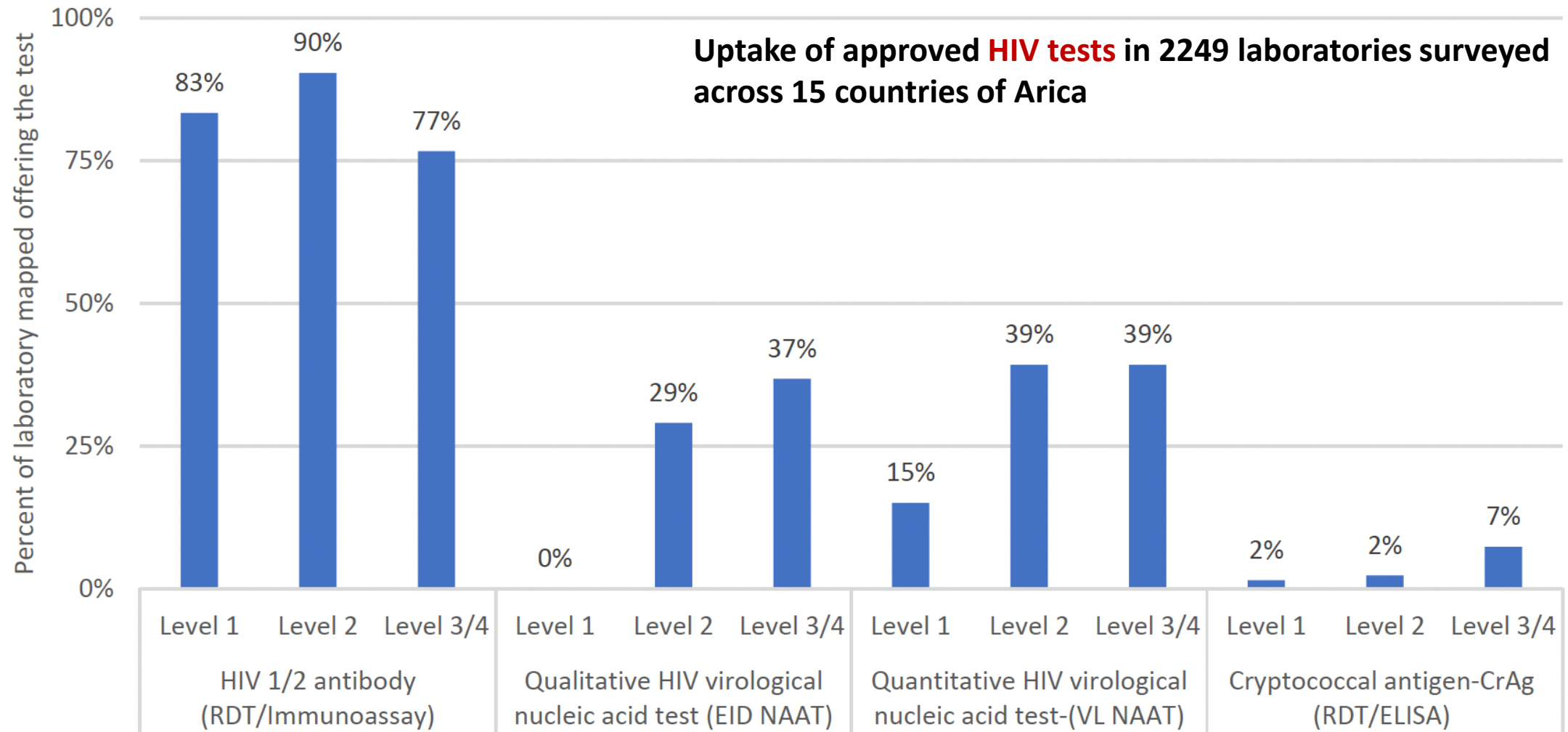
**but they do this based on evidence on technology performance with little attention to disease burden**

FIND and ASLM preliminary data)

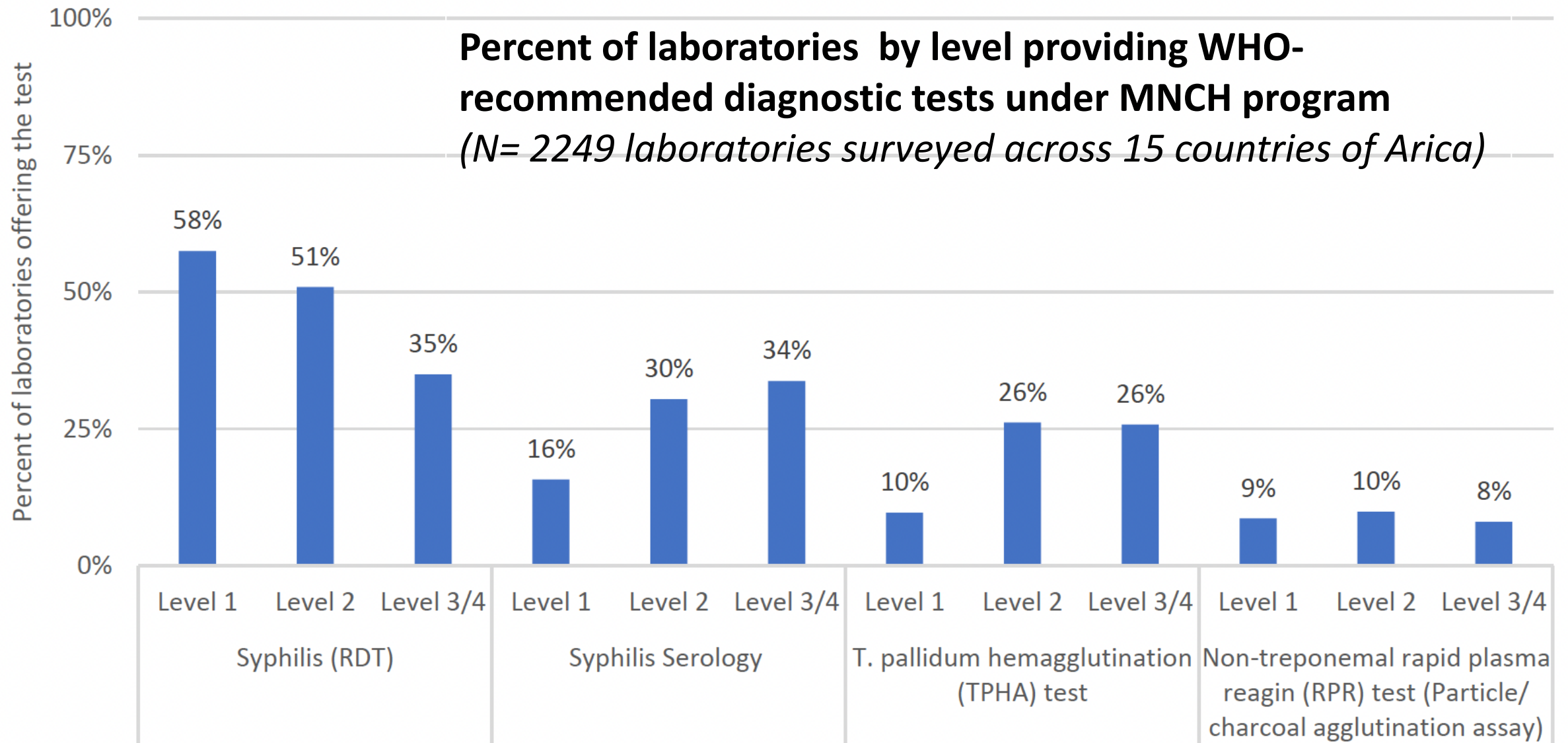
# Are tests adequately implemented, once they are approved?



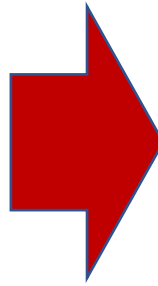
**Uptake of approved HIV tests in 2249 laboratories surveyed across 15 countries of Arica**



**Percent of laboratories by level providing WHO-recommended diagnostic tests under MNCH program**  
*(N= 2249 laboratories surveyed across 15 countries of Arica)*



- When(new) tests are implemented are they improving clinical and public health?
- Are they more cost effective than the previous standard of care?



No systematic data are collected are country level



Approval

Uptake

Impact

ASLM will continue to work with partners to shape the agenda towards the increased availability and access to context-relevant data on:

- Test performance across diseases
- Disease burden justifying the prioritization of tests for adoption/implementation
- Cost effectiveness of adopted tests for African settings



Image from <https://ieg.worldbankgroup.org/>



Thank You!



[www.aslm.org](http://www.aslm.org)