ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

LabDF
Laboratory Directors Forum

# Report of the High-level Meeting on Diagnostic Integration and Laboratory Systems Strengthening.

**Report** 27 - 28 April 2023
**Nairobi, Kenya**

# Table of Contents

# List of Abbreviations

| Abbreviation | Full term |
|---|---|
| AFCAD | Africa Collaborative Initiative to Advance Diagnostics |
| Africa CDC | Africa Centres for Disease Control and Prevention |
| API | Application programming interface |
| ASLM | African Society for Laboratory Medicine |
| AU | African Union |
| CAP/CTM | Cobas AmpliPrep/Cobas TaqMan |
| CHAI | Clinton Health Access Initiative |
| COVID-19 | Coronavirus disease 2019 |
| DNO | Diagnostic network optimisation |
| Dx | Diagnosis |
| EHLS | Eswatini Health Laboratory Service |
| EID | Early infant diagnosis |
| EMR | Electronic medical records |
| GAP | Global Access Program |
| GXP | GeneXpert |
| HCV | Hepatitis C virus |
| HR | Human resources |
| IDC | Integrated Diagnostics Consortium |
| IST | Integrated sample transportation |
| KHIS | Kenya Health Information System |
| KMHFL | Kenya Master Health Facility List |
| LabDF/LDF | Laboratory Directors Forum |
| MCH | Maternal-child health |
| M&E | Monitoring and evaluation |
| MOH / MoH | Ministry of Health |
| PAP | Papanicolaou test |
| PCR | Polymerase chain reaction |
| PEPFAR | President's Emergency Program for AIDS Relief |
| PM | Preventative Maintenance |
| POC | Point of care |
| PPE | Personal protective equipment |
| PPP | Public-private partnership |
| RSV | Respiratory syncytial virus |
| SA | South Africa |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 |
| SCM | Supply chain management |
| SMS | Short messaging service |
| TAT | Turn-around time |
| TB | Tuberculosis |
| TBD | To be determined |
| TWG | Technical working group |
| UHC | Universal Health Coverage |
| US | United States |
| VL | Viral load |
| WHA | Worth Health Assembly |
| WHO | World Health Organization |

# Background

Access to accurate and efficient diagnostic procedures is indispensable for preventing, diagnosing, and managing diseases, injuries and disabilities. Over the past decade, numerous countries have established substantial diagnostic platforms, primarily targeting priority diseases such as tuberculosis, HIV, and, more recently, coronavirus disease 2019 (COVID-19). These platforms often comprise versatile molecular instruments capable of conducting tests for multiple infectious diseases, including HIV, hepatitis C virus, hepatitis B virus, human papillomavirus and tuberculosis. Many of these assays have either already been received or are on the verge of obtaining regulatory approval from international bodies.

The emergence of the COVID-19 pandemic in 2020 prompted swift action from countries, who mobilised these existing platforms and repurposed them to combat the novel threat. This demonstrated the adaptability of health systems in striving to provide cost-effective, patient-centred services. The existing infrastructure and testing capacity built for these priority diseases have the potential to benefit numerous additional areas of healthcare. However, a common issue is that many countries operate these diagnostic systems in isolation, within individual disease programmes, which leads to inefficiencies and high costs.

Diagnostic integration encompasses multi-disease or integrated testing and presents a solution to expand the scope of healthcare services offered by the health system, while also generating cost savings for programmes already providing specific testing. It serves as a means to enhance testing services by using the investments already made and by ensuring more efficient utilisation of available resources and equitable access to diagnostics for those in need. Moreover, this approach aligns with key international and national healthcare initiatives, including the Maputo Declaration of 2008 and the recent resolutions to strengthen diagnostic capacity passed at the 152nd session of the World Health Organization Executive Board meeting and endorsed during the 76th World Health Assembly on 30 May 2023.

While several countries have successfully piloted integrated testing, scaling up this approach has proven to be a gradual process. This is mainly because diagnostic integration is far more intricate than merely deploying instruments capable of conducting multiple assays. Successful implementation involves simultaneously addressing multiple facets of the larger system. These include coordinated planning, regulatory approval, and strategic selection of products and sites to optimise testing site distribution to ensure the system meets demand and capacity requirements as outlined in the World Health Organization 2017 key considerations document. Furthermore, the establishment of robust quality management systems, encompassing standard operating procedures and user training, is essential. Capacity for supervision, monitoring and training is also a critical bottleneck to overcome. Proper inventory management, including procurement practices, is needed, as well as robust data systems that enhance network performance assessment, increase visibility and enhance service delivery.

To sustainably drive down costs and motivate ongoing research and development of more cost-effective integrated testing methods, sustained demand generation is paramount. In some instances, misalignment of stakeholder needs and interests has been a barrier to the successful integration of testing. Key stakeholders in this context encompass national laboratory services, programme managers (in areas such as tuberculosis, HIV, hepatitis, newborn and child health, and sexual and reproductive health), and international and bilateral agencies and organisations that provide financial and technical support to national health programmes.

With these considerations in mind, the African Society for Laboratory Medicine (ASLM) organised this high-level meeting with the overarching objective of convening countries and diagnostic stakeholders with the aim of facilitating discussions on experiences, critical operational challenges, best practices and lessons drawn from early adopter countries. These insights will inform future roadmaps and promote efficient adoption and scale up of diagnostic integration.

## Meeting objectives

### Share best practices.

Discuss policy frameworks, funding strategies, challenges, evidence and available diagnostic integration tools to inform interventions aimed at addressing identified gaps.

### Consult Laboratory Leaders.

Engage heads of laboratory services and national reference laboratories in consultations to identify key priorities for diagnostic integration.

### Draft Guidance Framework.

Develop a guidance framework document for diagnostic integration within laboratory networks of the African Region.

## Outcomes

### Prioritized List

Generate a prioritised list of key areas for diagnostic integration within the African Region.

### Common Position

Establish a common position for diagnostic integration within laboratory systems and networks of the African Region.

### Guidance Framework Document

Produce a draft guidance framework document detailing best practices and guidelines for diagnostic integration within laboratory networks of the African Region.

### Call to Action

Formulate a clear and actionable ‘Call to Action’ to accelerate the scaling up of diagnostic integration efforts.

| 97 | 53 | 44 | 15 |
|---|---|---|---|
| ATTENDEES | PHYSICALLY PRESENT | PARTICIPATING VIRTUALLY | COUNTRIES |

**LABORATORY DIRECTORS - HIV AND TUBERCULOSIS PROGRAMME MANAGERS - GLOBAL HEALTH EXPERTS - FUNDERS AND COLLABORATING PARTNERS.**

# Meeting overview

**The ASLM high-level meeting brought together 97 attendees, including 53 physically present and 44 participating virtually via Zoom conference connections. The participants primarily consisted of laboratory directors, HIV and tuberculosis programme managers from 15 countries, global health experts, funders and collaborating partners.**

The first day of the meeting encompassed four plenary sessions (Annex 1) featuring presentations from ASLM, collaborating partners, and funding agencies. Additionally, various countries shared their real-world experiences related to diagnostic integration and laboratory system strengthening. On the second day, a breakout session was organised, dividing countries into four groups. These groups shared their experiences to contribute to the formulation of a common position and refinement of approaches to diagnostic integration within laboratory networks in the African Region.

# Session Summaries and Key Takeaways

## Session 1

***Introduction and Opening Plenary on Diagnostic Strengthening Agenda***

Session 1 commenced with welcoming remarks from ASLM's Chief Executive Officer, Nqobile Ndlovu, and a representative from the Kenya Ministry of Health, Nancy Bowen. Subsequently, Talkmore Maruta, ASLM's Acting Director of Programmes, outlined the meeting objectives and expected outcomes. Presentations from key figures included George Alemji from the United States President's Emergency Program for AIDS Relief (PEPFAR), who discussed the 5-3 Strategy and leveraging existing investments for diagnostic integration. Fatim Cham-Jallow of the Global Fund shed light on an integrated approach for investments in laboratory systems. Smijlka De Lusigny from Unitaid shared insights on the multi-disease diagnostic landscape.

# Key Takeaways from Session 1

- **Achieving Universal Health Coverage (UHC)** necessitates a fundamental shift in service delivery and integration of services to meet the diverse needs of communities. While progress has been made in areas like HIV, tuberculosis and malaria, substantial testing needs remain across various diseases.
- **PEPFAR's 5-3 Strategy** focuses on ending the HIV/AIDS pandemic by 2030 while strengthening public health systems. Recommendations include establishing multi-disease policies, optimizing diagnostic networks, and embracing all-inclusive pricing.
- **The Global Fund** emphasises integrated and people-centred services. Integrated laboratory service delivery reduces turn-around times, enhances technology utilisation and improves cost-efficiency.
- **Unitaid's programmatic priorities** span across multiple diseases and include innovative approaches to diagnostics, like cervical cancer prevention. Unitaid drives market innovations and network optimisations.

# Session 2A/B

## Diagnostic Integration at National Level

### Success Stories on Integrated Testing Approaches

Session 2 featured two sessions of success stories on integrated testing approaches. In Session 2A, South Sudan's experience highlighted multi-disease testing, with achievements in testing for tuberculosis, HIV, severe acute respiratory syndrome coronavirus 2 and influenza. Zambia demonstrated the benefits of integrated testing to improving access and cost savings. Zimbabwe showcased its integrated sample transportation system. In Session 2B, Kenya shared its experience in optimising testing capacity across various diseases. Nigeria demonstrated success in leveraging GeneXpert machines for multiple tests. Eswatini showcased its sample transport system and negotiations for all-inclusive pricing. South Africa emphasised the value of connected laboratory diagnostics for programme monitoring and early alerts.

# Key Takeaways from Session 2A/B

- **South Sudan's approach transformed *in vitro* diagnostics,** merging in vitro and in vivo diagnostic disciplines, strengthened by information technology. (Figure 1, Figure 2)
- **Zambia's diagnostic network optimisation approach expanded testing for tuberculosis and HIV, with considerations for optimal site placement and cost savings.** Zambia's case demonstrated that it is feasible to expand tuberculosis programmes and improve HIV testing access within current capacity, although there is need to watch out for sites that end up operating over capacity. (Figure 3, Figure 4)
- **Zimbabwe's integrated sample transportation system increased cost efficiencies** by reducing unnecessary travel without specimens (mileage), utilising local service providers and implementing electronic specimen tracking. (Figure 5, Figure 6)
- **Kenya's approach optimised testing capacity,** emphasising the importance of data integration and near real-time analytics. (Figure 7)
- **South Africa underscored the significance of data analytics** for programme monitoring and transparency. (Figure 8)
- **Nigeria's GeneXpert utilisation expanded access** and reduced turn-around times. (Figure 9)
- **Eswatini's sample transport system** and Global Access Program (GAP) negotiations **ensured efficient testing**. (Figure 10) Additionally, **all-inclusive pricing** is necessary for transparency, upfront cost of equipment, facilitated budgeting, and improved service delivery.

# EVOLUTION OF DIAGNOSTIC INTEGRATION IN SOUTH SUDAN.

## (EVOLVING AND INTEGRATING)

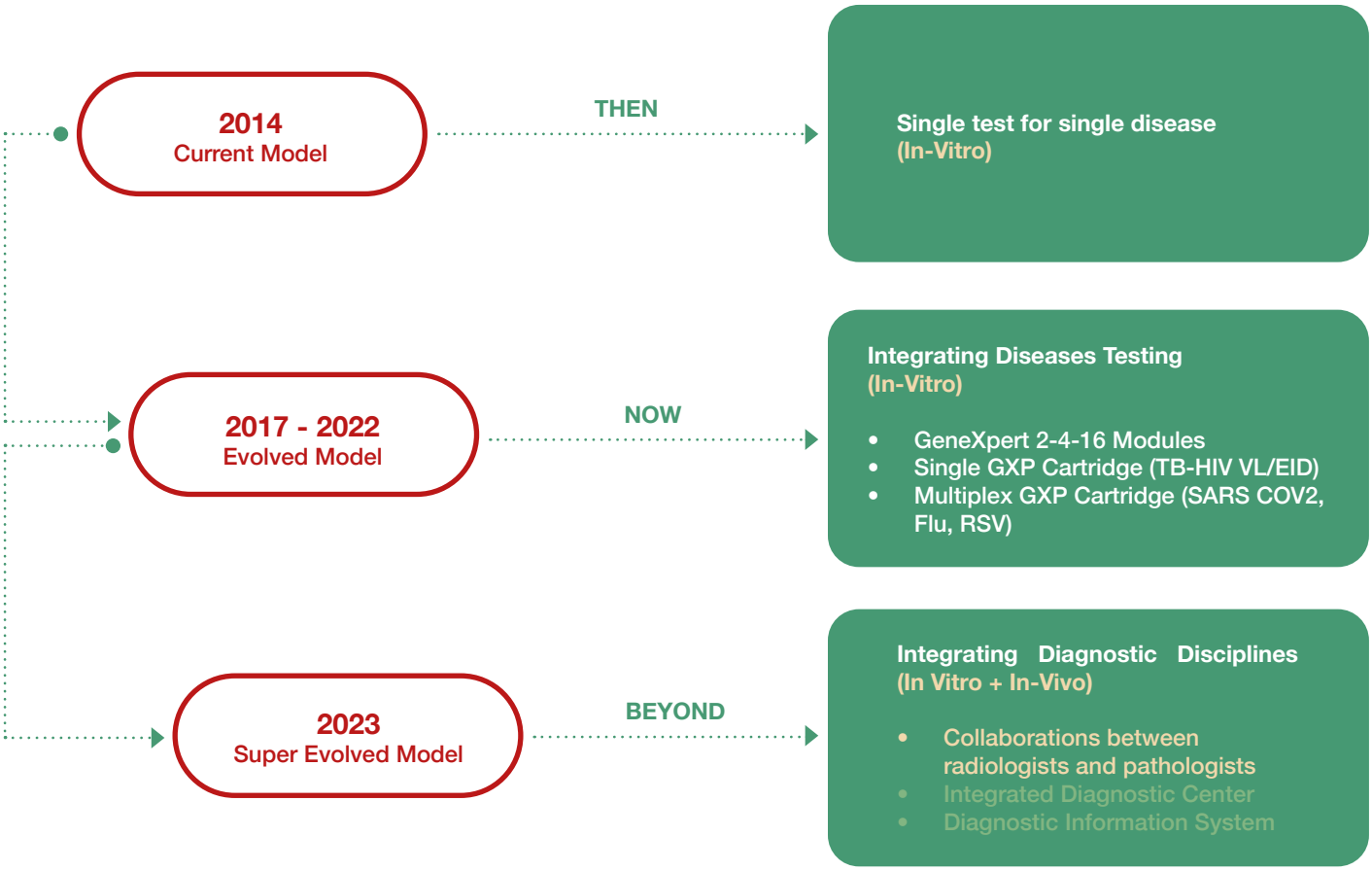



**Figure 1:** Diagnostic integration in South Sudan.

## MILESTONES AND IMPORTANT DATES

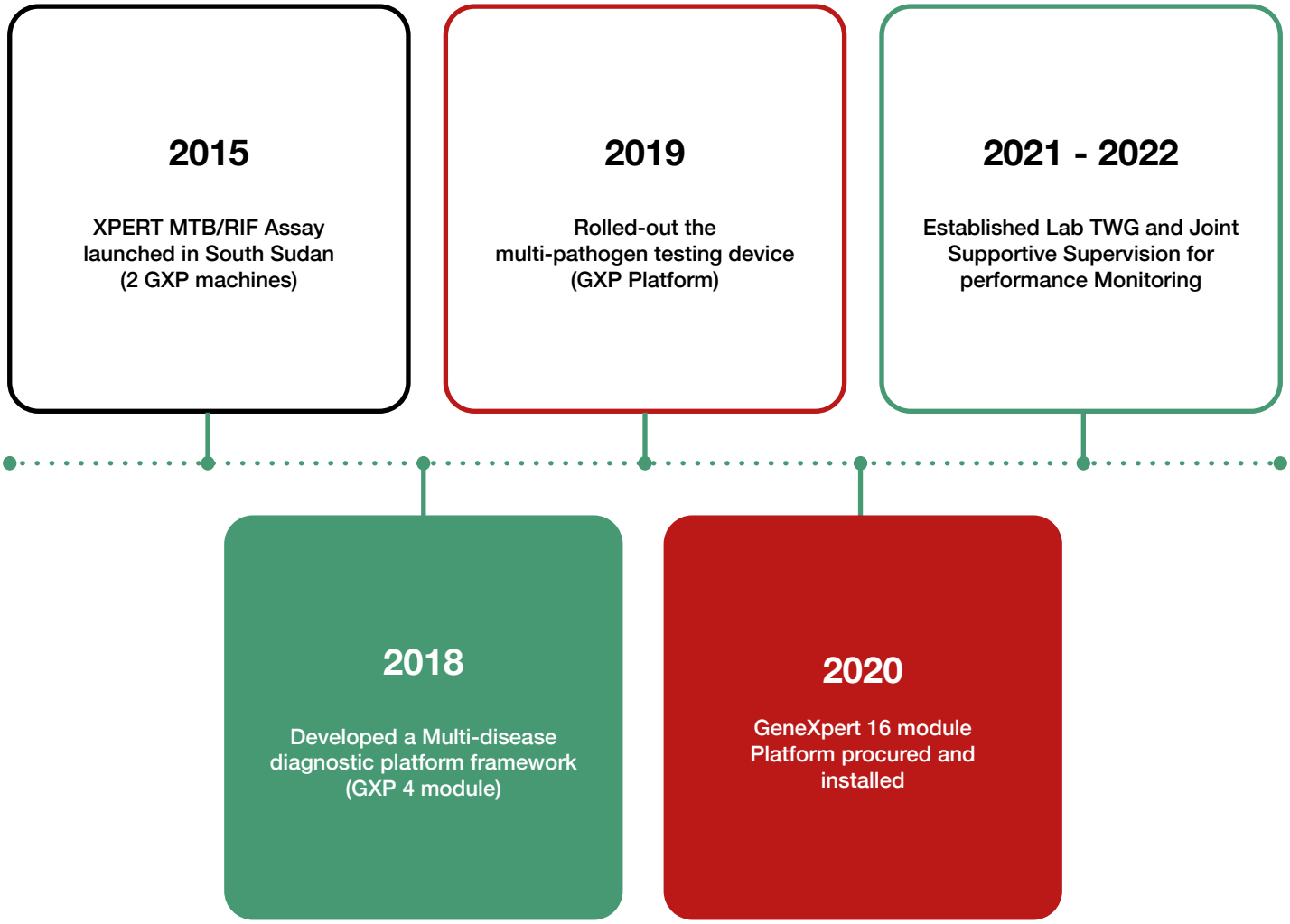



**Figure 2:** South Sudan diagnostic intergration milestones

# Methods

Using OptiDx software, we first established the **baseline diagnostic network** based on 2020 testing demand, referral linkages, testing sites, platforms, and costs for the HIV and TB programmes respectively.

Next, we incorporated **future testing demand** and programme expansion targets.

To improve access, we integrated priority HIV testing, including EID, on **GeneXpert platforms**, historically only utilized by the TB programme; and closed CAP/CTMs.

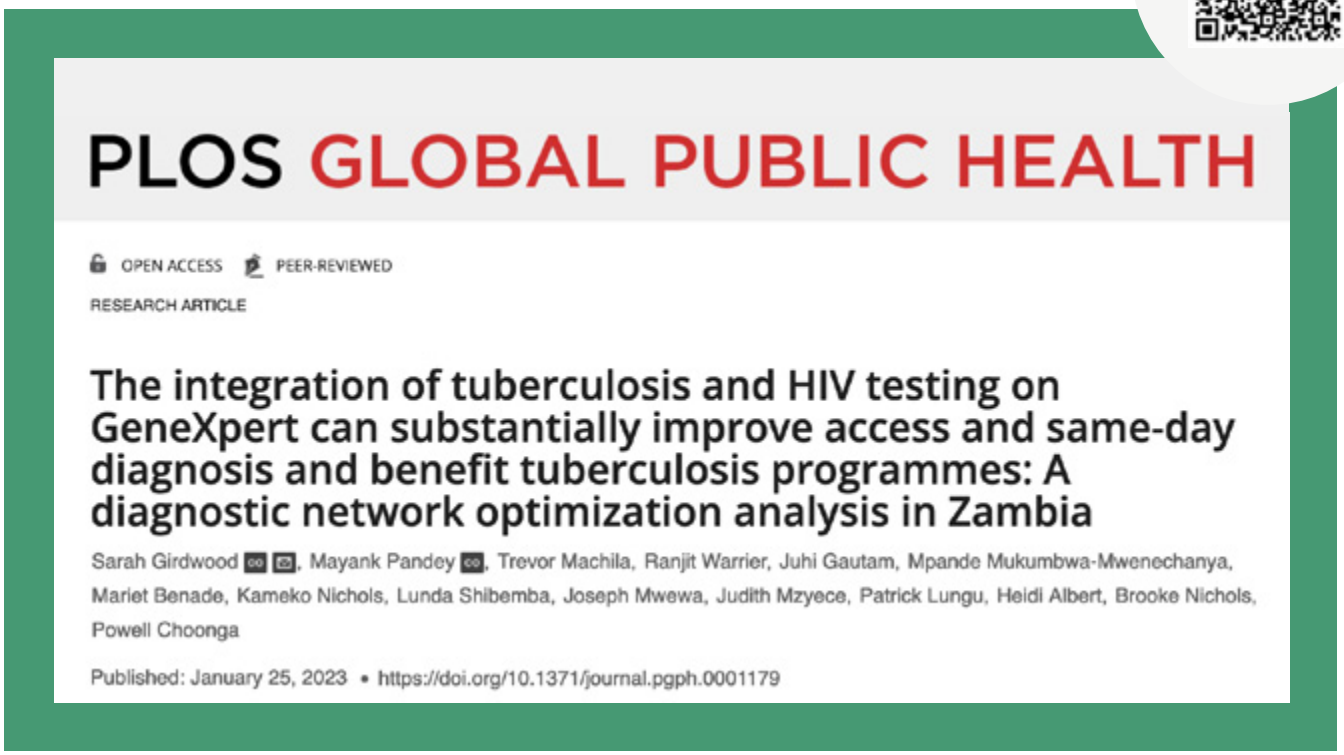
We then calculated the annualized device **cost**, variable cost/test, and sample transport cost for each scenario.

Lastly, we assessed how adding **additional devices** would impact results.

**Figure 3:** Diagnostic network optimisation approach used in Zambia Expand TB programme. The programme achieved full coverage, while improving access to early infant diagnosis and priority HIV viral load testing for pregnant and breastfeeding women and paediatric patients.

## Publications

**The integration of tuberculosis and HIV testing on GeneXpert can substantially improve access and same-day diagnosis and benefit tuberculosis programmes: A diagnostic network optimization analysis in Zambia**


PLOS GLOBAL PUBLIC HEALTH

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

The integration of tuberculosis and HIV testing on GeneXpert can substantially improve access and same-day diagnosis and benefit tuberculosis programmes: A diagnostic network optimization analysis in Zambia

Sarah Girdwood, Mayank Pandey, Trevor Machila, Ranjit Warrier, Juhi Gautam, Mpande Mukumbwa-Mwenechanya, Mariet Benade, Kameko Nichols, Lunda Shibemba, Joseph Mwewa, Judith Mzyece, Patrick Lungu, Heidi Albert, Brooke Nichols, Powell Choonga

Published: January 25, 2023 • https://doi.org/10.1371/journal.pgph.0001179

**Figure 4:** Publication on diagnostic integration in Zambia.

# IST Design and Planning

**Participatory approach: VL, EID Diagnostic Network optimization, Malaria, TB, Environment departments**

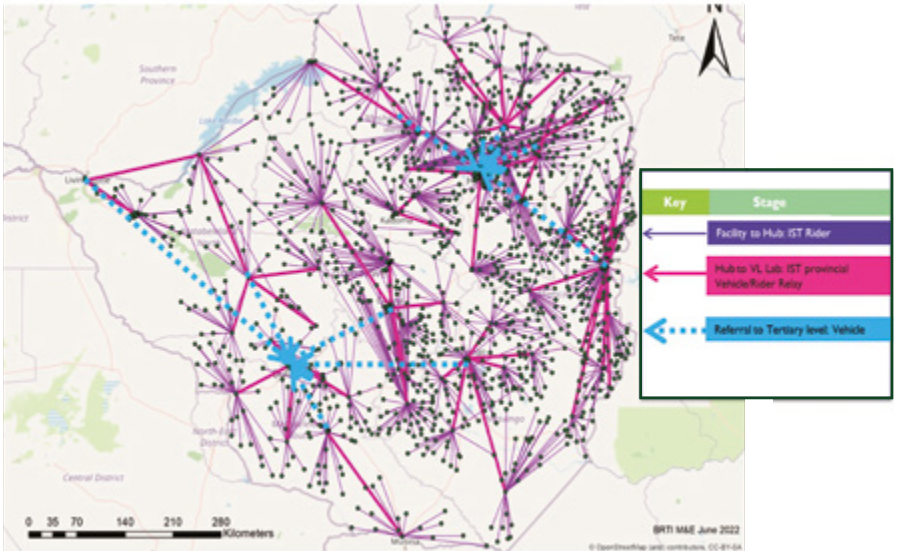
Designed to move both specimen and Results.

**Use of Lab-Equip software for optimisation and IST modelling**

- 341 clusters
- 280 motorbikes
- 8 provincial vehicles
- Rural cluster 2-3 times per week.
- Urban clusters 4-5 times per week

**Operational planning**

- HR
- PPE
- **Triple packaging**
- Fueling
- Service and maintenance




National Reference Laboratories | Central Hospital Laboratories | Provincial Hospital Laboratories | District/Mission Hospital | Rural Health Centers

# National IST Coverage 2019 - 2022

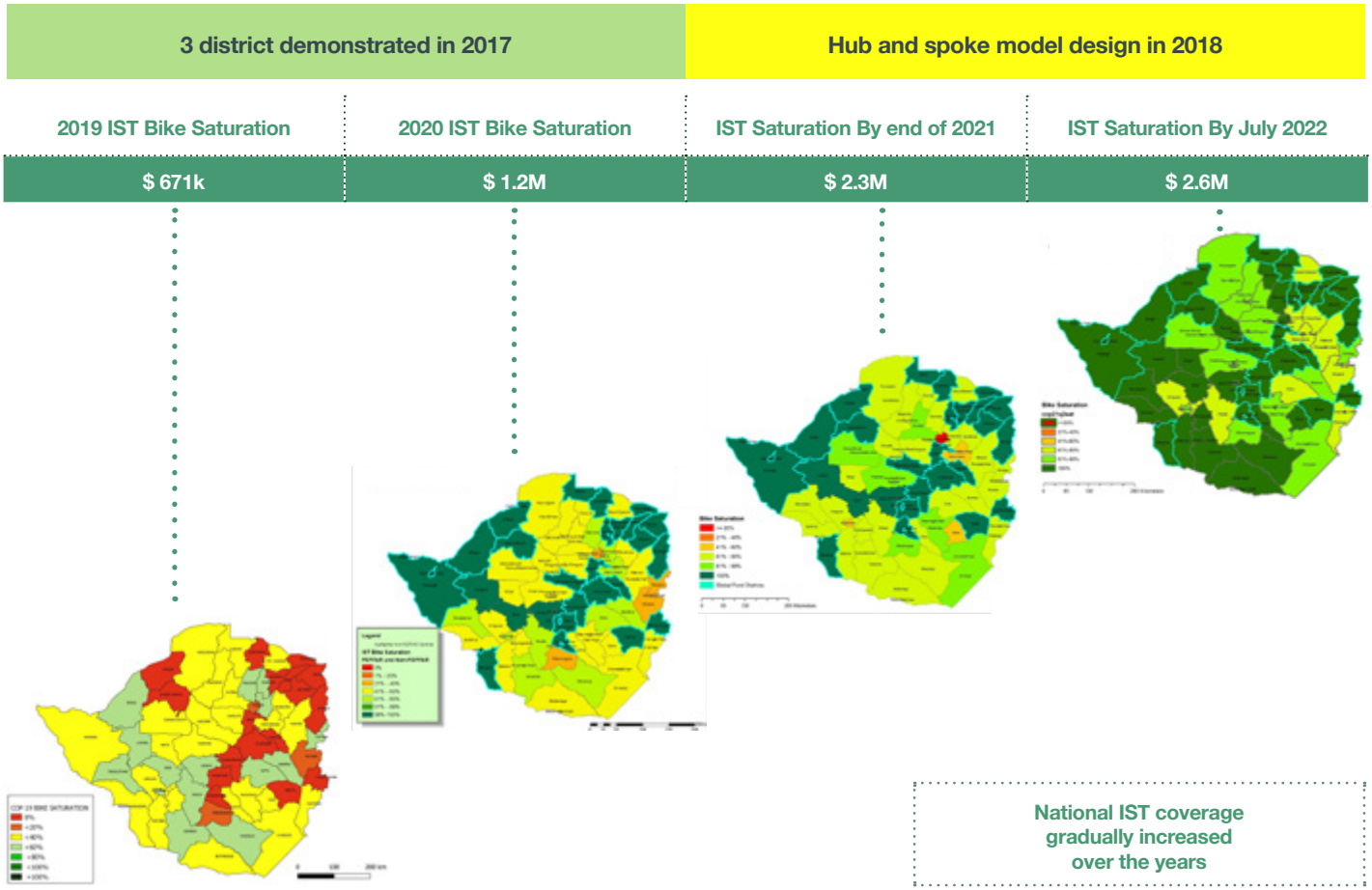



Figure 5: Integrated sample transportation system for improved diagnostic service delivery in Zimbabwe.

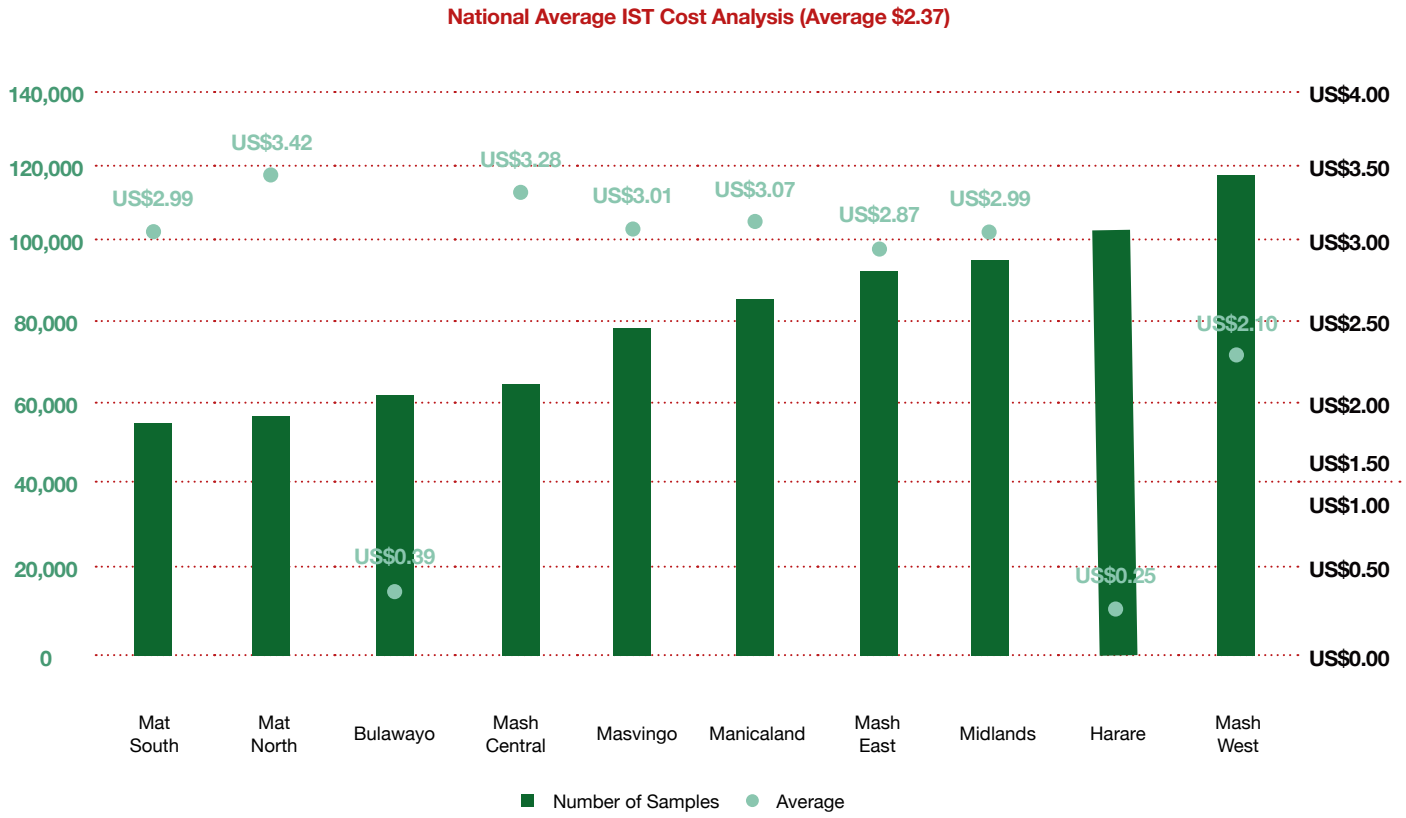



**Figure 6:** Integrated sample transportation system cost analysis for Zimbabwe.

## Kenya 'Timeline': The VL Story

| | | | |
|---|---|---|---|
| 2008 | • Testing Lab - 1<br>• No. of Sites - 4<br>• Samples - 102 | TAT 22 - 25 Days | • The Beginning |
| 2012 - 2013 | • Sample shipment to the lab a major challenge | TAT 22 - 25 Days | • Sample held for 2 weeks at the collection sites / hubs<br>• Clear VL networks established |
| 2013 - 2014 | • Within lab testing was a challenge (TATs >60 Days) | TAT 22 - 60 Days | • Onset of routine testing<br>• Workload overwhelming the equipment, HR and reagent stocks<br>• VL/EID TWG established |
| 2014 - 2015 | • Results not reaching the site<br>• 7 testing labs | TAT 24 - 35 Days | • Improve Labs Capacities<br>• National Database established<br>• Access of results by email/website introduced |
| 2015 - 2016 | • Results reaching the sites but not entered in patients | TAT 13 - 22 Days | • Lab clinical interface needed<br>• Referral networks reviewed<br>• Sample remote login implemented |
| 2017 - 2018 | • No. of testing labs - 10<br>• Testing Capacity 20 Abbot Roche CAPTCM | TAT 7 - 10 Days | • Scale up of remote login<br>• Improve relay of results by SMS text notification |
| 2019 - 2023 | • Integration with KMHFL<br>• Integration with client registry<br>• Harmonization ot the various systems to a unified system<br>• Integration with Kenya EMR<br>• Increase in POC Sites<br>• Increase of the number of testing labs to 12 | TAT 7 - 10 Days | • Scale up of remote login<br>• Improve relay of results by SMS text notification |

SOURCE: VL DIAGNOSTIC TESTING SERVICE DELIVERY IN KENYA - NANCY BOWEN

## EID/VL Interoperability and Integration

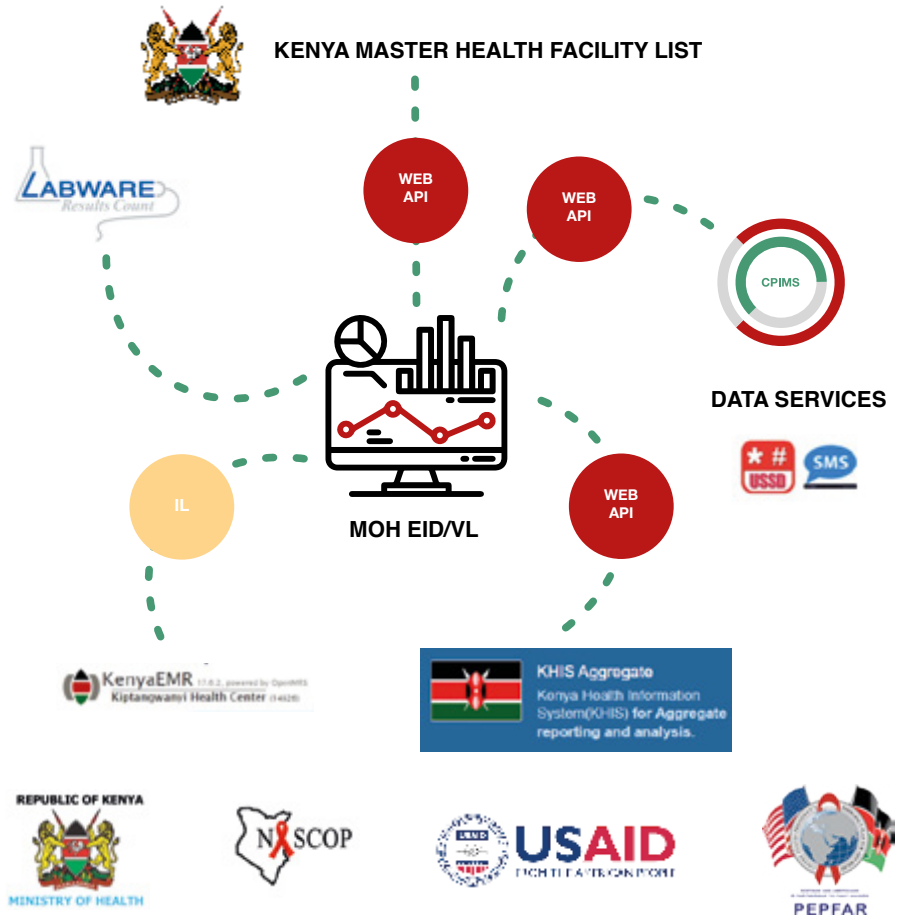
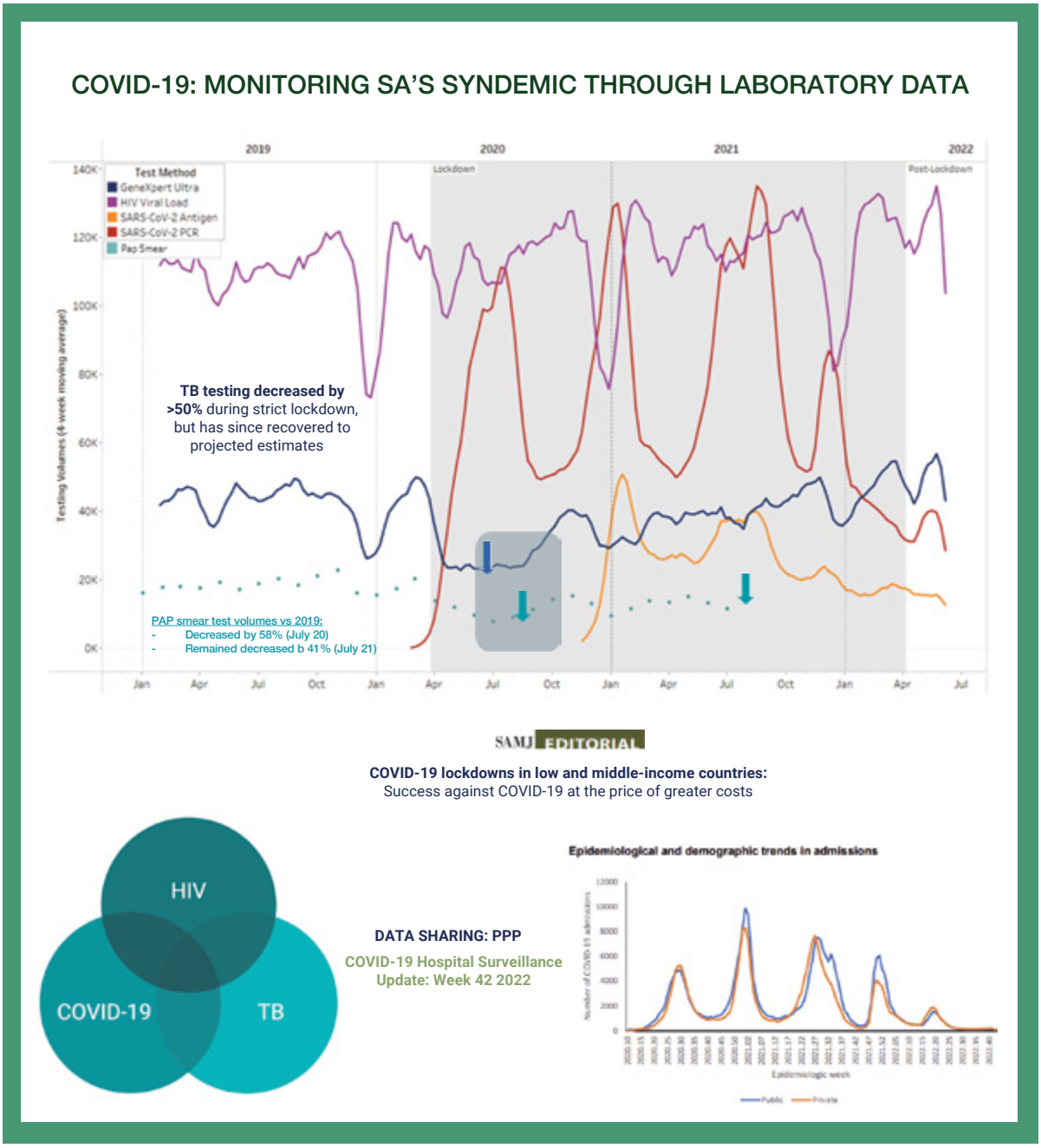



Figure 7: Diagnostic integration for improved HIV viral load and early infant diagnosis test result turn-around time in Kenya.

University of the Witwatersrand
WITS DIH
Diagnostic Innovation Hub




NATIONAL HEALTH LABORATORY SERVICE

**Figure 8:** Establishment of data sharing public private partnerships for integrated monitoring of tuberculosis, HIV, COVID-19 and cancer screening in South Africa.

# Diagnostic Integration

## Thematic Areas

| | HIV Program | TB Program |
|---|---|---|
| Program set-up cost | Regulatory Framework | Regulatory Framework |
| | Policies | Policies |
| | Quality Assurance | Quality Assurance |
| | Training | Training |
| Testing costs | Testing Commodities | Testing Commodities |
| Systems costs | **Dx Instruments** | |
| | Service and Maintenance | |
| | **Logistics / Commodity** | |
| | Human Resource | |
| | **Sample Transportation** | |
| | Waste Management | |
| | M&E | |
| | Data Management | |
| | Results Delivery | |

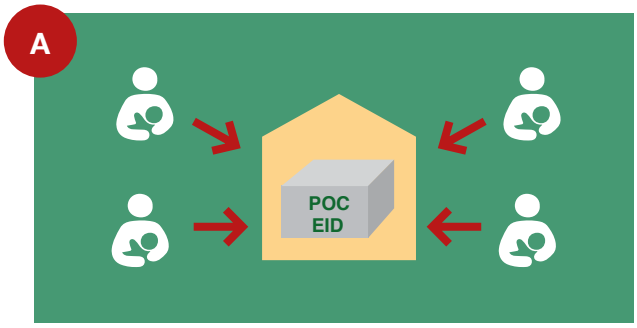
Cost shared by integrating services

There are many areas where diagnostic intergration can yield improved efficiency, not only through higher utilization of the platforms, but also through leveraging and combining laboratory support systems, such as supply chain, training, mentorship, and connectivity.

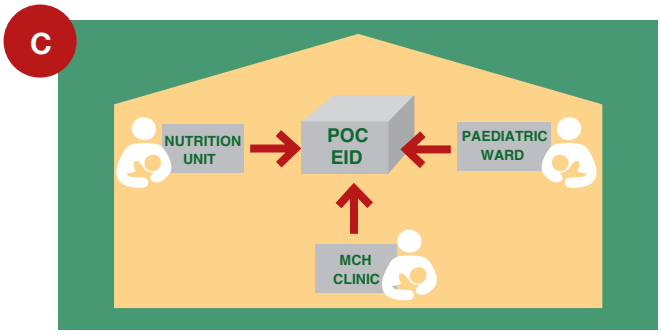
**WHO, 2017:** Considerations for adoption and use of multidisease testing devices in integrated laboratory networks

**A combination of integrated testing strategies can be used to increase access to testing; expand case finding; decrease result-to-caregiver TAT; optimize platform utilization**

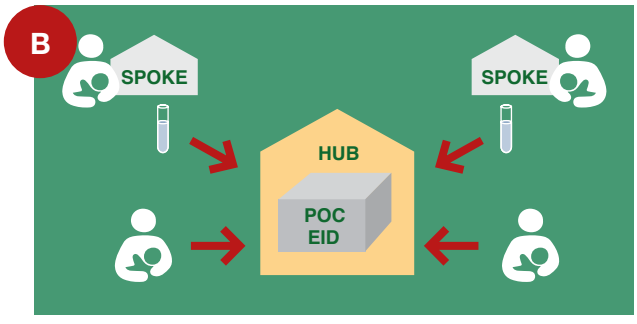
### Onsite Testing
Receive samples directly from clients and perform POC EID tests on site




### Multiple Entry Point Testing
Stand-alone or hub testing sites receive samples from different units or wards within the same health facility




### Hub-and-Spoke Networks
Hub sites provide testing for patients at that site and for spoke sites. Nearby spoke sites send samples to the hub sites for testing




### Multi-Disease Testing
Process different types of POC tests (e.g. EID, TB, other)

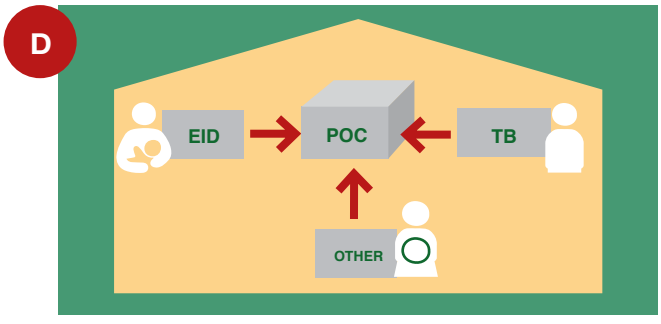



**Figure 9:** Diagnostic integration strategy in Nigeria.

## What is included and not included in price of a test?

**The price per test includes :**

- all products and services offered by the supplier needed to produce a test result [A-D],
- all freight and logistics costs associated with these products and services [E],
- and any adjustments needed to account for reagents that do not produce a direct patient result [F-G].

Pricing Agreements

| Category | | Description |
|---|---|---|
| A | Reagents and Proprietary Consumables | All reagents and single-use consumables manufactured by the supplier and needed to produce a test result in the lab |
| B | Non-Proprietary Consumables | Single-use consumables not manufactured by the supplier but considered necessary to produce a test result in the lab |
| C | Service and Maintenance | Cost of servicing and maintaining any equipment including routine maintenance, repairs & replacements, and any necessary updates |
| D | Equipment Placement | Cost of all equipment needed to run the samples as well as initial installation, basic connectivity, and ongoing training for lab technicians |
| E | Freight and Logistics | Cost of export fees, export clearance, carriage, insurance, and delivery to the testing site. Does not include local taxes or duties. |
| F | Control and Calibration | Cost of reagents required for control and calibration purposes that do not produce a patient result need to be factored into end price per tes |
| G | Errors and Failures | Replacement of failed reagents resulting from system errors; corrective action training for labs with high rates of user errors |

The price per test does not include ancillary costs, for example, those associated with sample collection, sample transport, laboratory staff time, laboratory infrastructure, generic lab supplies (e.g. primary collection tubes, disposable gloves, etc.), inventory management, or general administration and overhead costs

## Key Performance Indicators Tracking

Pricing Agreements

| No. | Description | Target |
|---|---|---|
| 01. | Percentage of instruments that receive at least 1 (one) PM visit per year from the date of installation | 100% |
| 02. | Mean time to response for equipment breakdown: time lapsed from time issue first reported to the time a follow-up plan is communicated to the customer | 48 hours |
| 03. | Mean time to repair: average # of calendar days lapsed from time issue first reported to job completion | ≤ 5 days |
| 04. | Percentage of instruments that have ≤2 instrument outages per quarter. An outage is defined as any instrument breakdown* that 1) prevents the release of patient results for more than two (2) hours and 2) occurs less than 3 months after a preventative maintenance visit or total service call for the same issue that was previously repaired. | 100% |
| 05. | Average percentage “uptime” per quarter | >85% |
| 06. | Average percentage of failed tests due to machine or human error | <5%* |
| 07. | Percentage of Quarterly Reports submitted on-time per the terms of the subcontract | 100% |
| 08. | Average percentage “uptime” of automated reporting system | >95% |
| 09. | Percentage of batches that are delivered to the customer with a 12-month shelf-life | 100% |
| 10. | Percentage of line items delivered in full and on time. In-full is measured against agreed ordered quantities. On-time is defined as 14 days prior/7 days after the current committed goods available date. | >90% |

**Having and monitoring Key Performance Indicators in addition to the inclusive pricing agreements is critical or ensuring reliable and efficient diagnostic service delivery and accountability. EHLS already has quarterly reports for KPI review with some vendors towards continuously improving diagnostic services provided.**

**Figure 10: Lessons from Eswatini on pricing agreements.** Knowing what is included in pricing agreements and the key performance indicators to monitor

# Session 3

## From Best Practices to Action

### Section 1: Devising optimal multi-disease testing using cost-benefit analysis

Session 3 delved into cost-benefit analysis for optimal multi-disease testing. It also featured group discussions on drivers for diagnostic integration and its role in achieving person-centred care and UHC. (Figure 11, Figure 12, Figure 13 and Figure 14)

## Key Takeaways from Session 3

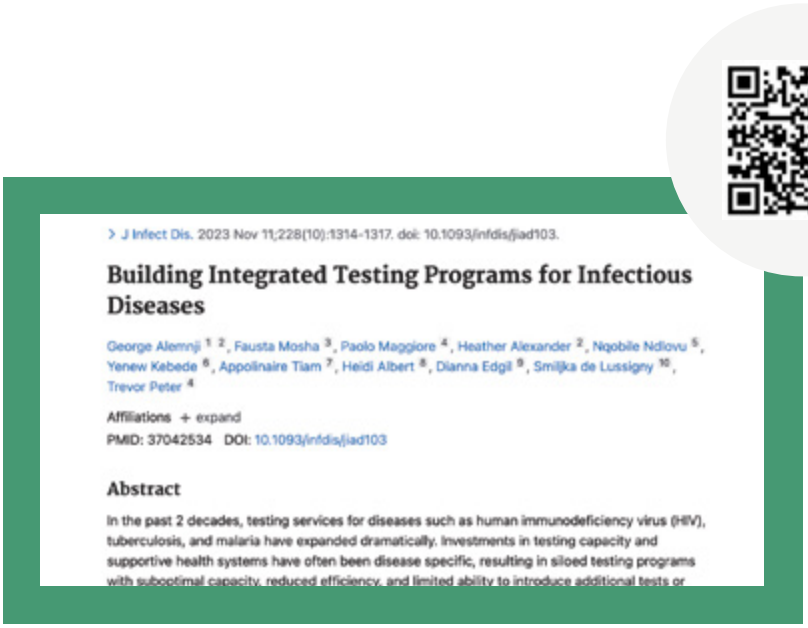
- **Reducing testing costs** involves addressing reagent and instrument costs, network expenses and patient costs.
- **Tools aid in cost reduction** and include: integration, global access prices, all-inclusive pricing, diagnostic network optimisation and point-of-care testing.
- **Successful integration** depends on conducive government environments, policy support, stakeholder engagement, demand creation, data-driven programming and funding diversification.
- **Industry involvement** and collaboration from planning to implementation are crucial.

**All-inclusive Pricing: Procurement contracts are moving toward all-inclusive models with comprehensive terms, and instrument placement rather than purchase.**

| Cost components | Standard | Standard+ | Standard++ | All-Inclusive Price /Test | All-Inclusive Price / Result |
|---|---|---|---|---|---|
| Reagents | Separate | Bundled price per test | Bundled price per test | Bundled price per test including instrument rental payments | Bundled price per result including instrument rental payments |
| Controls and Calibrators | Separate | | | | |
| Consumables | Separate | | | | |
| Service and Maintenance | Separate | Separate | | | |
| Instrument | Separate | Separate | Separate | | |
| Instrument Status | Purchased | Purchased | Purchased | Leased / Placed | Leased / Placed |

Figure 11: CHAI presentation on all-inclusive pricing models CHAI presentation on all-inclusive pricing models

## What will it take to ensure full Diagnostic Integration?




### Five Recommendations to Enable Diagnostic Integration

- Establish multi-disease policies
- Use common health systems
- Optimize diagnostic networks
- Adopt all-inclusive pricing
- Share innovation across diseases

**Figure 12.** PEPFAR recommendations to enable full diagnostic integration.

## Key enablers of integration

### Integration of laboratory services can be achieved through multiple avenues

| Best practice | Example | Enabling | Achieved By |
|---|---|---|---|
| Develop system-level intelligence | • Digital dashboards for monitoring system performance, consistently updated with real-time data for decision-making | • Key decision-makers to exploit cost and logistical efficiencies, informed by high-quality data and evidence | • Deploying unified digital solutions throughout the laboratory system<br>• Aggregating data in centralized repositories<br>• Training key stakeholders |
| Leverage supportive services across priority diseases | • Specimen referral services serving HIV, TB and other priority diseases | • Supportive services to utilize existing infrastructure to expand service delivery, operational efficiency, access and patient outcomes | • Undertaking DNO to optimize network resources<br>• Empowering Laboratory Directorates as key owners and coordinators of system-level services |
| Leverage diagnostic resources for multiple-pathogen diagnosis | • Diagnostic analyzers are utilized for diagnosis of multiple pathogens | • Samples from patients with co-infection can be analyzed at a single laboratory, improving patient management | • Unifying management of diagnostic analyzers; contracting new diagnostic resources through all-inclusive pricing |

THE GLOBAL FUND

**Figure 13.** The Global Fund recommendations for enablers of integration.

Integrated Diagnostics Consortium

## Diagnostic Network Optimization

Diagnostic network optimization (DNO) is a geospatial analytical approach that aims to better align demand and testing capacity in a way that improves access and generate efficiencies.

**Diagnostic network optimization (DNO) is used to**

- Analyze the current diagnostic network
- Recommend the optimal type, number and location of diagnostics and associated sample referral network to achieve national health goals
- Minimize overall network costs subject to applied (access) constraints
- Leverage network efficiency to recommend a cost-effective network design

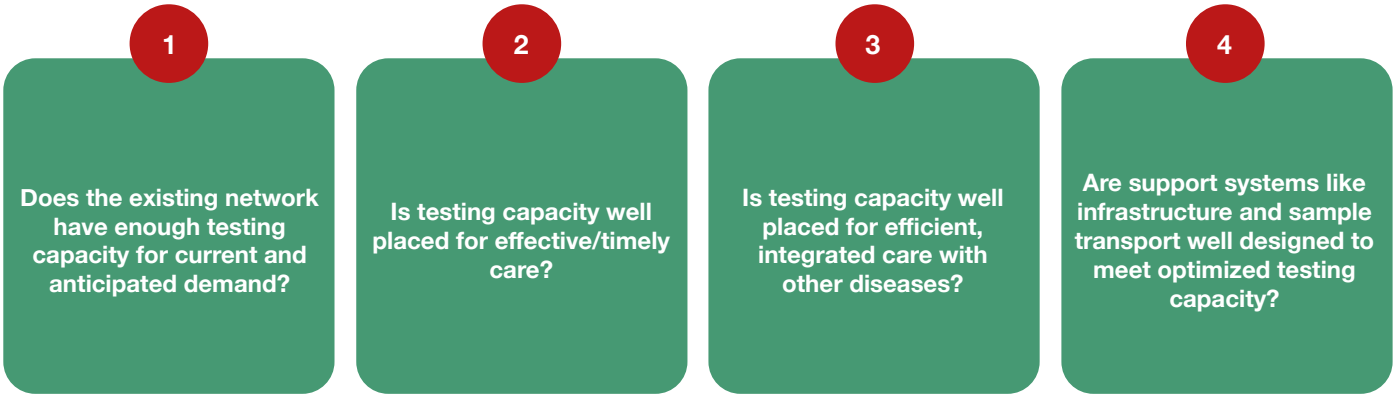



**Figure 14.** Utility of diagnostic network optimisation in supporting diagnostic integration. (UNITAID)

# Section 2

### Focused group discussion

### What it takes to scale up test integration in Africa (ASLM)

During this 1.5-hour session, participants shared their thoughts on current integration efforts, their satisfaction levels and the challenges they identified. Various facets of integration were examined, including policymaker awareness, coordination, sensitization of countries and engagement of stakeholders beyond clinicians and laboratories. The discussion covered both positive and negative aspects of integration, emphasizing strengths and areas needing improvement. Topics encompassed the roles of national governments, civil society, donors, partners, the WHO, healthcare workers, industry, programme collaboration, supply chain, funding, success measurement and data for decision-making. In essence, the Focused Group Discussion collected valuable insights and perspectives to advance effective diagnostic integration, aiming to enhance clinical outcomes, device utilization and cost-effectiveness at the national level. These were then organized as a List of Priorities for Diagnostic Integration in the African Region (Annex 2).

## Key takeaways from the Focused Group Discussion:

- **Governments need to create a conducive environment that supports this diagnostic integration.** Zambia has integrated all in-country platforms like the technical working groups into one, to avoid silos, so they have a platform where they meet. This is just one way of ensuring that a conducive environment is created for diagnostic integration.
- **Support integration via a formal policy.** There is a need for policy direction and guidance from governments themselves in terms of how they would like to proceed with diagnostic integration. We need to determine how many countries do have a policy on diagnostic integration and we commit to work together to achieve that.
- **Wider stakeholder engagement beyond just the laboratory is needed.** Diagnostic integration should not only come from the testing laboratory side but also from the systems and disease programme sides to ensure that we can achieve the cost effectiveness that we need for integration.
- **It starts with demand creation.** We can integrate the technologies and systems but if there is no demand we cannot succeed. One example are GeneXpert machines that are now being moved from one place to another, because of underutilisation. Engagement beyond the laboratory will be key, and it should also include the public and private sector, as well as the patients or recipients of care.
- **Drive programming with data from integrated systems.** The information we are gathering from our laboratory information management systems should also be integrated with programme data, so that both can inform us in terms of the needs of integration, as well as whether we are achieving our goals
- **Move away from vertical funding.** Funding is also key but, as we see in most countries, funding already comes in silos that are created by existing funding models. There is a call for governments to make conscious decisions towards mobilising our donors and partners to move away from vertical programmes towards integration at all levels as we plan for funding or as we request for funding from these donors.
- **Involve industry throughout.** Industry should be involved through the entire planning and implementation processes. The classic case of Zambia showed the success of including the industry in the planning stages, including the quantification. Discussions are already taking place with industry, because this is where the technology is coming from; thus, industry always needs to understand country plans and have an opportunity to advise us on what is possible and what is in the pipeline.

# Section 3

## Breakout group work

### Refining approaches to diagnostic integration within laboratory networks of the African Region

In the last section of Session 3, all countries participated in breakout group work. Countries were allocated into four groups of four to six participants to refine approaches to diagnostic integration within the laboratory networks of the African Region. Each group shared their perspectives on the critical success factors for achieving effective scale-up of diagnostic integration in support of person-centred care and UHC by reflecting on the following questions:

01. **What is the purpose of diagnostic integration?**

02. **What can we achieve through effective diagnostic integration?**

03. **What are the most effective drivers of diagnostic integration?**

04. **What can our governments do to support diagnostic integration?**

These perspectives contributed to shaping a Call to Action on diagnostic integration that reflects the goals of the Laboratory Directors Forum and its partner organisations (Annex 3).

### Closing Plenary

In closing, the ASLM Chief Executive Officer, Nqobile Ndlovu, recognised the value of defining common standing and defining common approaches as the sustainable way forward for scaling up diagnostic integration and strengthening integrated laboratory systems for better health. On behalf of the Laboratory Directors Forum, the Chair, Susan Nabadda, reiterated the same sentiments and is looking forward to a successful implementation of the practices that have been shared from this year and beyond.

### Conclusion and Way Forward

The ASLM high-level meeting served as a pivotal platform for stakeholders across the African Region to converge and deliberate on the pressing issues surrounding diagnostic integration within laboratory systems and networks. The wealth of insights shared and the collaborative spirit exhibited during this gathering underscore the significance of a coordinated approach to diagnostics.

In this meeting, we successfully achieved the initial outcomes we set out to accomplish. We collaboratively created a prioritized list of key areas (Annex 2) for diagnostic integration within the African Region, providing a basic roadmap for our efforts. Additionally, this list represents a common position regarding diagnostic integration within laboratory systems and networks across the region, fostering a unified approach. Furthermore, we made substantial progress by brainstorming content that will feed into a guidance framework document that outlines best practices and guidelines for diagnostic integration within laboratory networks in the African Region, which will serve as a valuable resource for our collective efforts. Lastly, our collective efforts culminated in the formulation of a clear and actionable 'Call to Action,' which will serve as a driving force to accelerate the scaling up of diagnostic integration endeavours (Annex 3, Annex 4). These achievements mark the first crucial steps towards enhancing healthcare outcomes and accessibility within our region.

### Acknowledgments

ASLM thanks the Kenya Laboratory Directorate for hosting the meeting, all laboratory leaders, disease programme heads, representatives and global stakeholders who contributed to the planning and who attended the meeting. ASLM extends special thanks to Hologic for their financial contribution to this high-level meeting on diagnostic integration.

# Annexes

## Annex 1.

### Meeting Agenda

**Click Link to meeting presentations or Scan the QR code**
Laboratory Directors Forum Diagnostic integration meeting Kenya 27-28 Apr 2023

| Time | Session Description | Speaker |
|---|---|---|
| | **Day 1: Thursday 27 April 2023** | |
| | **Session 1: Opening Plenary: The Diagnostics strengthening agenda. Chair: Susan N. Nabadda (Uganda) & Henry Kohar (Liberia)** | |
| 08:30 - 09:00 | ***Coffee and Registration: Please sign the registration sheet each day*** | |
| 09:00 - 09:15 | Welcome remarks and opening session. | ASLM<br>WHO<br>Kenya MoH |
| 09:15 - 09:20 | Expected outcomes of the workshop | ASLM |
| 09:20 - 09:35 | Strengthening diagnostics capacity using an integrated approach (Lessons from the past informing the future) | WHO |
| 09:35 - 09:50 | PEPFAR's 5-3 Strategy - Leverage existing investments for effective diagnostic integration | PEPFAR |
| 09:50 - 10:05 | An integrated approach for Laboratory systems investments: Informing future Investments in Diagnostic Integration | The Global Fund |
| 10:05 - 10:20 | Multi-Disease Diagnostic Landscape For Integrated Management Of HIV, HCV, TB And Other Co-infections | Unitaid |
| 10:20 - 11:00 | **Group photo and Tea break** | |
| | **Session 2A: Diagnostic Integration at National Level: Success stories on integrated testing approaches Chair: Joseph Bitilinyu-Bangoh (Malawi) and Mbenga Roguet Nina (Gabon)** | |
| 11:00 - 11:45 | Diagnostic Integration: Current status and opportunities for improvement. | South Sudan<br>Zambia |
| 11:45 - 12:10 | Question and Answer | |
| 12:10 - 12:30 | Integrated Testing and referral networks | Zimbabwe |
| 12:30 - 13:00 | Question and Answer | |
| 13:00 - 14:00 | Lunch Break | |

| Session 2B: Success stories – continued<br>Chair: Zikan Koroma (Sierra Leone) | | |
|---|---|---|
| 14:00 - 14:30 | Integrated Robust data systems | Kenya<br>South Africa |
| 14:30 - 14:45 | Question and Answer | |
| 14:45 - 15:30 | • Integrating systems: Innovation and transparency in service level agreements for uninterrupted supplies<br>• Examples of all-inclusive pricing<br>• Industry perspective | Nigeria<br>Eswatini<br>Industry |
| 15:30 - 15:45 | Question and Answer | |
| 15:45 - 16:00 | Tackling the waste management problem | South Sudan |
| 16:00 - 16:30 | Question and Answer | |
| 16:30 - 16:45 | Wrap up | ASLM |

| Time | Session Description | Speaker |
|---|---|---|
| | **Day 2: Friday 28 April 2023** | |
| **Session 3: From best practices to action:<br>Chair: Joseph Nyandwi (Burundi) & William Addo Mills Pappoe (Ghana)** | | |
| 08:30 - 09:00 | ***Coffee and Registration: Please sign the registration sheet each day*** | |
| 09:00 - 09:15 | Devising optimal multi disease testing using cost–benefit analysis | CHAI |
| 09:15 - 09:30 | Question and Answer | ALL |
| 09:25 - 10:30 | **Focused Group Discussion**<br>*From best practices to action: What it Takes to scale up test integration in Africa.* | ASLM |
| 10:30 - 10:45 | Coffee break | |
| 10:45 - 12:00 | **Group work:** *Refining approaches to diagnostic Integration within Laboratory Networks of the Africa Region* | ALL |
| 12:00 - 13:00 | Feed-back and general discussion | ALL |
| 13:30 - 14:00 | Lunch Break | ALL |
| 14:00 - 15:00 | Call to Action | ALL |
| 15:00 - 15:30 | Wrap up and Closing Plenary | |

## Annex 2.

### List of Priorities for Diagnostic Integration in the African Region

This list of priorities emerged from the outcomes of the group discussion. A designated note taker summarized these key areas at the conclusion of the discussion for the group's consensus. These priorities reflect the critical areas where action is needed to advance diagnostic integration efforts in the African Region, ultimately leading to improved healthcare services and outcomes for the population.

01. **Policy Frameworks.** Develop and implement policy frameworks at the national level to support and guide diagnostic integration efforts, ensuring alignment with broader healthcare goals.

02. **Data Integration.** Establish robust systems for data integration that merge laboratory information with programme data to inform decision-making and resource allocation.

03. **Stakeholder Engagement.** Foster multi-stakeholder engagement beyond the laboratory to include disease programmes, the public and private sectors, and patient representatives.

04. **Demand Creation.** Strategically create demand for integrated diagnostic services through public awareness campaigns and engagement with healthcare providers.

05. **Funding Diversification**. Advocate for funding diversification and moving away from vertical programmes and towards integrated diagnostics, and for securing resources for implementation.

06. **Industry Collaboration.** Collaborate with diagnostic industry partners throughout the planning and implementation phases to leverage technological innovations and ensure alignment with country plans.

07. **All-Inclusive Pricing.** Promote all-inclusive pricing models for diagnostic instruments, reagents and services to facilitate budgeting and improve service delivery.

08. **Diagnostic Network Optimisation.** Optimise laboratory networks for increased test access, efficiency and cost reduction.

09. **Capacity Building.** Invest in capacity building, including training, supervision and quality management systems, to ensure skilled human resources for diagnostic integration.

10. **Policy Advocacy.** Advocate for supportive government policies and directives that create conducive environments for diagnostic integration.

## Annex 3.

### Call to Action

**Integrating diagnostics across disease programmes to deliver high-quality, people-centred integrated service and care**

We, the Laboratory Directors Forum (LabDF), a forum launched in September 2022 under the African Society for Laboratory Medicine (ASLM) and Africa Centres for Disease Control and Prevention (Africa CDC) for African leaders in laboratory services to provide space and infrastructure for laboratory leaders to develop a unified voice to shape agendas, define priorities and harness individual countries' strengths, capabilities and successes to further build laboratory capacity on the continent, during the 'High-level Meeting on Diagnostic Integration and Laboratory systems strengthening meeting' held 27-28th April 2023 in Nairobi, Kenya,

**Acknowledging** the 2008 Maputo Declaration calling for donors and development partners to commit to working collaboratively and with coordination from the national governments to support the strengthening of laboratory systems in order to create one unified, integrated national diagnostic network;

**Acknowledging** the 2023 World Health Assembly (WHA) resolution for strengthening diagnostics capacity, calling for high-quality integrated diagnostic interventions and integrated networks to tackle all diseases;

**Prioritising** the aim to achieve Universal Health Coverage (UHC) and deliver quality people-centred integrated service and the need to expand access to essential diagnostics;

**Deeply Concerned** by continued investments in only vertical disease programmes and testing capacity that is disease-specific without enabling greater integration, resulting in suboptimal capacity, reduced efficiency, limited ability to introduce additional tests and increased cost for health services;

**Aware** of the Africa CDC Africa Collaborative Initiative to Advance Diagnostics (AFCAD) that promotes the diagnostic agenda in Africa through better-coordinated and synergised efforts that align with the priorities of the ministries of health of Member States;

**Cognisant** of emerging evidence of the cost effectiveness of diagnostic integration due to reduction of testing costs, testing turn-around times, costs of servicing and maintenance, training and human resources needs and in line with the Africa CDC recent guideline on building testing capacity for epidemic prone diseases;

**Appreciating** the significant investments and efforts previously made by countries, donors and partners in expanding access to diagnostic testing across diseases;

**Noting** the existence of innovative new diagnostics with easily scalable multi-disease testing capabilities creating opportunities for diagnostic integration;

**Make this call for:**

- All Member States to conduct diagnostic network optimisation as a tool to define the optimal instruments mix, identifying the most appropriate locations where instruments should be placed and designing the referral network linkages across the revised network.

- All Member States, donors and partners to actively transition from mostly vertical disease programmes and disease testing capacity to more integrated diagnostic systems, including building diagnostic capacity for priority epidemic prone-diseases, and for national governments to create a conducive policy environment and take the lead in diagnostic integration, while donors and partners commit to supporting diagnostic integration for both conventional testing and point-of-care testing.

- All Member States to adopt all-inclusive pricing and combination tests to lower costs, expand test access, improve efficiency and simplify supply chains through bundling of tests.

- Expansion of the scope of the molecular pricing database on global access pricing standards available to all Member States, in order to increase transparency and standardisation in pricing and procurement.

- Expansion of the use of point-of-care tests, especially multiplex and combination tests, to improve patient access to tests and health outcomes and to reduce the burden on patients accessing care.

- Collection, collation and use of data to inform decision-making and continuously monitor cost effectiveness of diagnostic integration. National Governments shall remain custodians of such data housed in centralised data repositories with capabilities to link with and inform other public health interventions like surveillance, preparedness and response to public health threats.

- Civil society to raise awareness and advocate for equitable access to people-centred, high-quality, appropriate diagnostic to all populations and settings, and for civil society to lead and facilitate empowerment of communities and recipients to improve demand for integrated testing and utilisation of tests results to inform care and treatment.

- Industry to continuously facilitate and support diagnostic integration through creation of solutions and innovations in sample collection, transporting testing and digital tools for result utilisation for multiple testing on same instruments.

- ASLM, in collaboration with Member States, Africa CDC, the World Health Organization (WHO), donors and partners to develop a monitoring and evaluation framework with national and regional key performance indicators to track progress in diagnostic integration in the Africa Region.

- Development of a continental framework on diagnostic integration that Member States can adapt, adopt and domesticate, including a guidance document to clearly articulate purpose, identify key considerations, steps, coordination of funding and technical assistance, anticipated challenges and possible mitigation measures for diagnostic integration.

**12 May 2023**

## Annex 4.

### Action Items from the Call to Action

**Action Items from the Call to Action on integrating diagnostics across disease programmes in order to deliver high-quality, people-centred integrated service and care**

| Call to Action | Action Items | Responsibility / Partners | Timeline |
|---|---|---|---|
| All Member States to conduct diagnostic network optimisation as a tool to define the optimal instruments mix, identifying the most appropriate locations where instruments should be placed, and designing the referral network linkages across the revised network. | Conduct survey on status of DNO among the 55 AU Member States | ASLM (in collaboration with IDC) | Q1 2024 |
| | Conduct DNO in TBD countries (based on outcome of survey above) | IDC | Q3 2024 |
| | Track countries that implement recommendations of DNO and corresponding impact | ASLM, LDF | Q2 2024 |
| Member States, donors and partners to actively transition from mostly vertical disease programmes and disease testing capacity to more integrated diagnostic systems. National governments to create conducive policy environment and take lead in diagnostic integration while donors and partners commit to supporting diagnostic integration for both conventional testing and point-of-care testing | Conduct survey to identify countries with national policy on diagnostic integration | | |
| | Establish current status and monitor national level progress of diagnostic integration using standard integration readiness assessment tool – jointly developed by ASLM and partners | ASLM | Q4 2023 |
| | Provide technical assistance on developing national policy on diagnostic integration to TBD countries (to depend on output from above | ASLM | From Q2 2024 |
| All Member States to adopt all-inclusive pricing and combination tests to lower costs, expand test access, improve efficiency, simplify supply chains through bundling tests | Conduct survey to identify countries using all-inclusive pricing and combination tests | ASLM | Q2 2024 |
| | Countries include this provision for bundled pricing at policy level | LDF | Q1 2025 |
| Expand the scope of the molecular pricing database on global access pricing standards available to all Member States in order to increase transparency and standardisation in pricing and procurement. | Structured updates of the pricing database. | ASLM, CHAI and IDC | Q3 2023 and Ongoing |
| | Reaching out to additional manufacturers | CHAI | |
| | Track usage of the database for making informed decisions | ASLM | |
| Expand the use of point-of-care tests, especially multiplex and combination tests, to improve patient access to tests and health outcomes, and to reduce the burden on patients accessing care. | Subcommunity of Practice on EDL and community testing | ASLM (LabCoP) | Q1 2024 |
| Collection, collation and use of data to inform decision-making and continuously monitor cost effectiveness of diagnostic integration. National Governments shall remain custodians of such data housed in centralised data repositories with capabilities to link with and inform other public health interventions like surveillance, preparedness and response to public health threats | Develop a protocol for measuring cost effectiveness of diagnostic integration | CHAI | TBD |
| | Support Member States to establish centralised data repositories with capabilities to link with and inform other public health interventions like surveillance, preparedness and response to public health threats | ASLM AFRICA CDC | TBD |
| ASLM, in collaboration with Member States, donors and partners develop a monitoring and evaluation framework with national and regional key performance indicators to track progress in diagnostic integration in the Africa Region | Develop a monitoring and evaluation framework to track implementation of diagnostic integration across the Africa Region | LabDF | Q4 2024 |
| | Collect data and share regular updates on status of implementation of diagnostic integration in the Africa Region | ASLM | Q3 2023 and Ongoing |
| Development of a continental framework on diagnostic integration that Member States can adapt, adopt and domesticate. The guidance document to clearly articulate purpose, identify key considerations, steps, coordination of funding and technical assistance, anticipated challenges and possible mitigation measures for diagnostic integration. | Develop continental guidance framework on diagnostic integration | LabDF, (ASLM ACDC) | Q1 2024 |
| | Support Member States domesticate and operationalise continental framework within 3 years | LDF | Q1 2025 and ongoing |

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LabDF
Laboratory Directors Forum

# High-level Meeting on Diagnostic Integration and Laboratory Systems Strengthening

## Report 27 - 28 April 2023

**Nairobi, Kenya**

**aslm.org**