



Scaling Impact:

Integrated Diagnostic Networks for
TB Elimination in Africa.

Contents

- i. Africa TB Burden**
 - Africa's crisis and WHO recommendations
- ii. The Roche Portfolio**
 - Mycobacteria portfolio and Technology
- iii. The Integrated Approach**
 - Sustainability, Resilience and Lifecycle
- iv. Roche Commitment and Capabilities**
 - Consulting, Workflow proof and Our Africa Footprint.

Africa's TB Burden

Disease Burden and Diagnostic progress - 2025

"This is a crucial period. Even as we must strive to meet the commitments from the second United Nations high-level meeting on TB, we have entered a new period of scarcity. WHO is committed to working with donors, partners and affected countries to mitigate the impact of funding cuts, find innovative solutions, and mobilize the political and financial commitments needed to End TB"

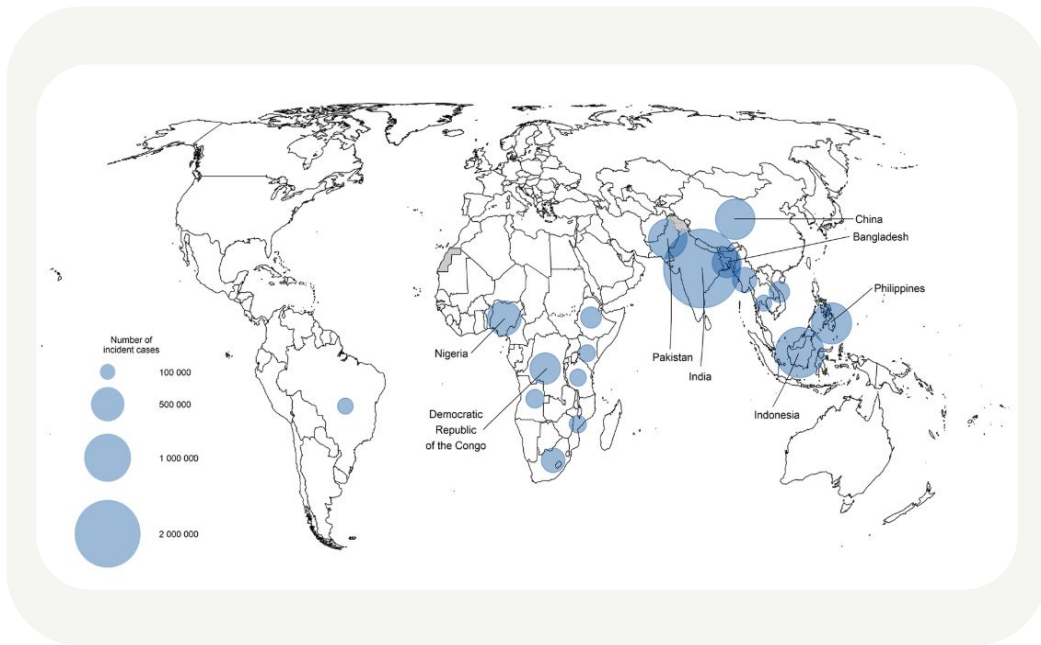
Dr Tedros Adhanom Ghebreyesus - DG, WHO

WHO Africa - 2025

2.5 million people fell ill with TB
(25% of the 10.7m global incidence)

410,000 people died from TB
(33% of the 1.23m global deaths)

74% of all newly diagnosed TB used mWRD
(Higher than global average of 54%)



Aligning with 2025 WHO Diagnostic Recommendations

Current Status

End TB Indicator	2025 Milestone	Status	2030 Milestone	2035 Milestone
TB incidence rate	-50%	-28%	-80%	-90%
Number of deaths	-75%	-46%	-90%	-95%
Catastrophic costs	0%	47%	0%	0%

We have the potential to catch up

With thoughtful country-wide implementation of mWRDs, in conjunction with active case finding, we can treat more patients.

Strategic Blueprint

- Detection:
 - 100% Initial mWRD Testing
 - Move from microscopy, ensure every presumptive TB case receives an upfront mWRD.
 - Universal Resistance Testing - Immediate DST to map Rifampicin and Pre-XDR resistance profiles.
- Rapid Triage Workflows
 - Combine clinical screening with Digital Chest X-Rays to fast-track patients directly to Molecular confirmation.
- Efficiency
 - Optimize Multi-Disease Platforms - Maximize existing laboratory networks by integrating TB assays onto underutilized Molecular diagnostic instruments.
 - Utilize Validated alternative samples (pediatric stool, tongue swabs) on molecular diagnostic platforms.



Tuberculosis is everywhere. Having the ability to rapidly diagnose and scale capacity when its most urgent is essential to a national priority programme response plan.

Roche Mycobacteria Portfolio



Are they at risk?

DIGITAL X-RAY / AI
for screening/triage



What do they need now?

DIAGNOSE
for *M. tuberculosis*



Is the treatment regimen correct?

REFLEX TB POSITIVE
for drug resistance markers



How can I manage their care?

REFLEX TB NEGATIVE
for prevalence nontuberculous

Partnering

cobas® MTB

cobas® MTB-RIF/INH

cobas® MAI

What Defines Us?

The only MC-aNAAT approved by WHO



**World Health
Organization**

**Prequalification of
Medical Products**

Quality and implementation science repeatedly practiced within large HIV and TB programmes globally, supporting public health objectives

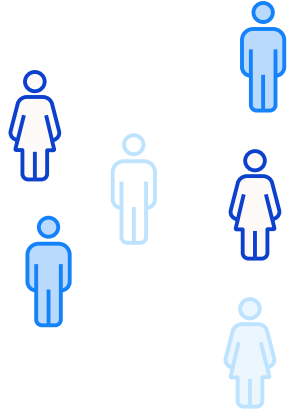
Proven Quality with Implementation Support

- **WHO Prequalification:** The only tests approved in the Moderate Complexity classification detecting tuberculosis plus rifampicin and isoniazid resistance.
- **Low- and Middle-Income History:** Over a decade of HIV programme excellence; supplying 100+ million tests to LMICs.
- **Healthcare Consulting:** Expert consultation teams that work with Ministries of Health and priority programmes to achieve strategic national health objectives.

Diagnostic technologies to the intended population

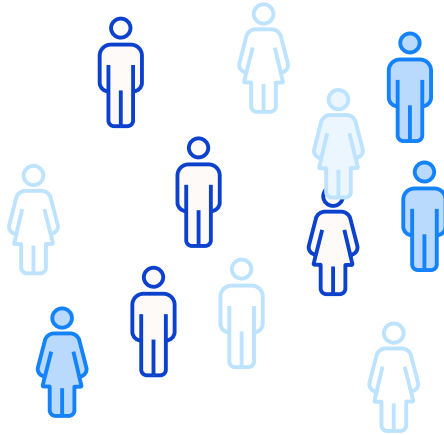
NPOC-NAATs

portable system, peripheral settings
no drug resistance



LC-aNAATs

automated, low volume
rifampicin detection



MC-aNAATs

automated, high volume
rifampicin and isoniazid



HC-rNAATs

specialized skills
broader resistance



Diagnosis of tuberculosis and detection of drug-resistance rapid communication. Geneva: World Health Organization; 2024. <https://doi.org/10.2471/B09111>

Note: Additional WHO diagnostic classifications are not represented. Eg: Point of Care (POC), Low-Complexity Manual NAATs (LC-mNAATs), Lateral Flow Urine Lipoarabinomannan Assay (LF-LAM), Next Generation Sequencing (NGS), First-line LPA (FL-LPA), Second-line LPA (SL-LPA).

Integrated Testing Approach

Diagnostic integration is urgently needed

Current landscape is fragmented, inefficient and unsustainable as countries pursue health sovereignty



Today - fragmented landscape:

- Isolated clinics, multi-stop patient journeys
- Siloed, non-communicating disease programs
- Resource and capability duplication across diseases
- Uncoordinated budgeting, redundant investment

Ideal - integrated future:

- Holistic care, one-stop patient visits
- Collaborative disease programs with shared synergies
- Unified disease-agnostic diagnostic networks
- Optimized spending, better patient outcomes with less

Integration has never been more needed – and more possible

Integration is key to sustaining hard-won public health progress

Governments, donors, NGOs, and local organizations all see integration as a future imperative



Catalyzes sustainability

- Creates **efficiencies** in staffing, supply chain, and infrastructure
- Lowers costs by improving utilization of **existing platforms**
- Enables **transparency** and **coordination** to support enhanced budgeting and self-sustaining systems



Builds resilience

- Fosters **holistic patient experience**, addressing co-morbidities and providing preventive care
- Offers multi-disease testing in a **one-stop shop**
- Enables programs to leverage investments and capabilities to rapidly respond to **pandemics** and **outbreaks**

Integration requires collaboration across all levels of health systems

From clinics, to supply chains and sample transport, to labs and instruments, to data systems



“Several technologies already exist that can test for many different diseases and analytes and/or be used for various monitoring approaches; therefore, **WHO strongly supports and encourages diagnostic integration** across diseases and programmes.”

At the program level:



Supply Chain & Procurement



Financing



Training & HR

At the lab network level:



Specialties & Workflows



Sample Collection & Transport



Quality Assurance



Data Management

At the instrument level:



HIV



TB



HPV



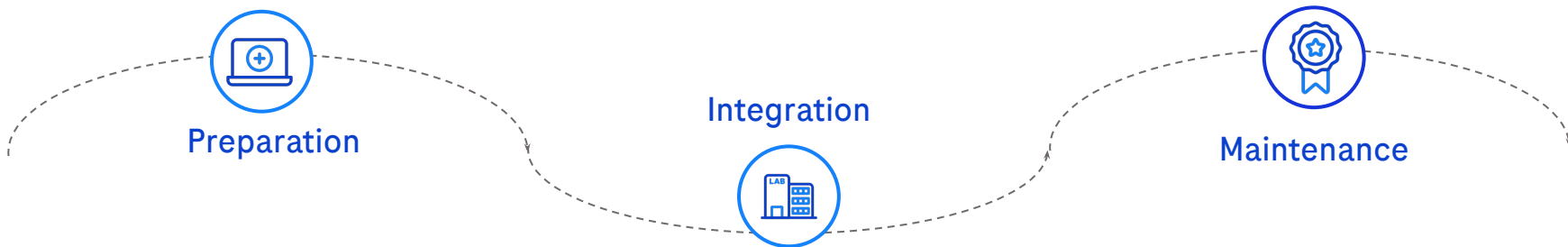
HCV / HBV



Omnichannel

What is needed to integrate

Successful and sustainable integration considers the complete diagnostic lifecycle



- Assess lab networks and identify spare capacity and parallel systems
- Optimize technology deployment based on geography and population need
- Coordinate planning and above-program budgets
- Establish policies and protocols that support integration
- Leverage best practices

- Deploy versatile instruments for multi-disease testing
- Ensure lab network readiness (workflows, sample transport, automation, training)
- Optimize procurement for cost and supply chain efficiency
- Implement SLAs and performance monitoring
- Utilize flexible, interconnected data systems

- Provide ongoing staff training and upskilling
- Perform continuous improvement to increase efficiency and quality
- Conduct quarterly reviews and KPI monitoring

New use case: integration to accelerate toward TB 2030 targets

Instruments in place for HIV have spare capacity to take on TB testing at a time when resources are constrained

Fight against TB is off track

We will miss the 2030 TB elimination goals if we do not implement new testing approaches

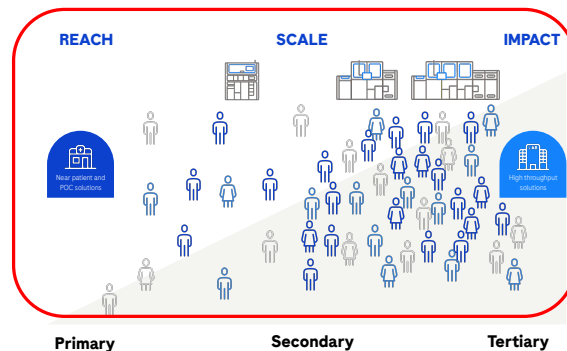
Today's challenges:

- Approach relies on facility-based, passive case finding with low-complexity, low-throughput instruments
- “Missing millions”: 2.5M people with TB went undiagnosed in 2025
- Only 46% of those diagnosed received a mWRD, which the WHO recommends as the initial test for all people being evaluated for TB due to their speed and ability to detect resistance
- INH resistance is more common than RIF resistance but is tested for less frequently



Opportunity to accelerate TB progress through integration

- [WHO consolidated guidelines](#) recommend both low and moderate complexity mWRD for detection of TB: optimize networks by **strategic placement of instruments based on their respective strengths and population needs**
- Roche instruments already in place for HIV are well-suited for TB at secondary (district/referral) and tertiary level settings and for active case finding, complementing the extensive near-patient offerings in countries



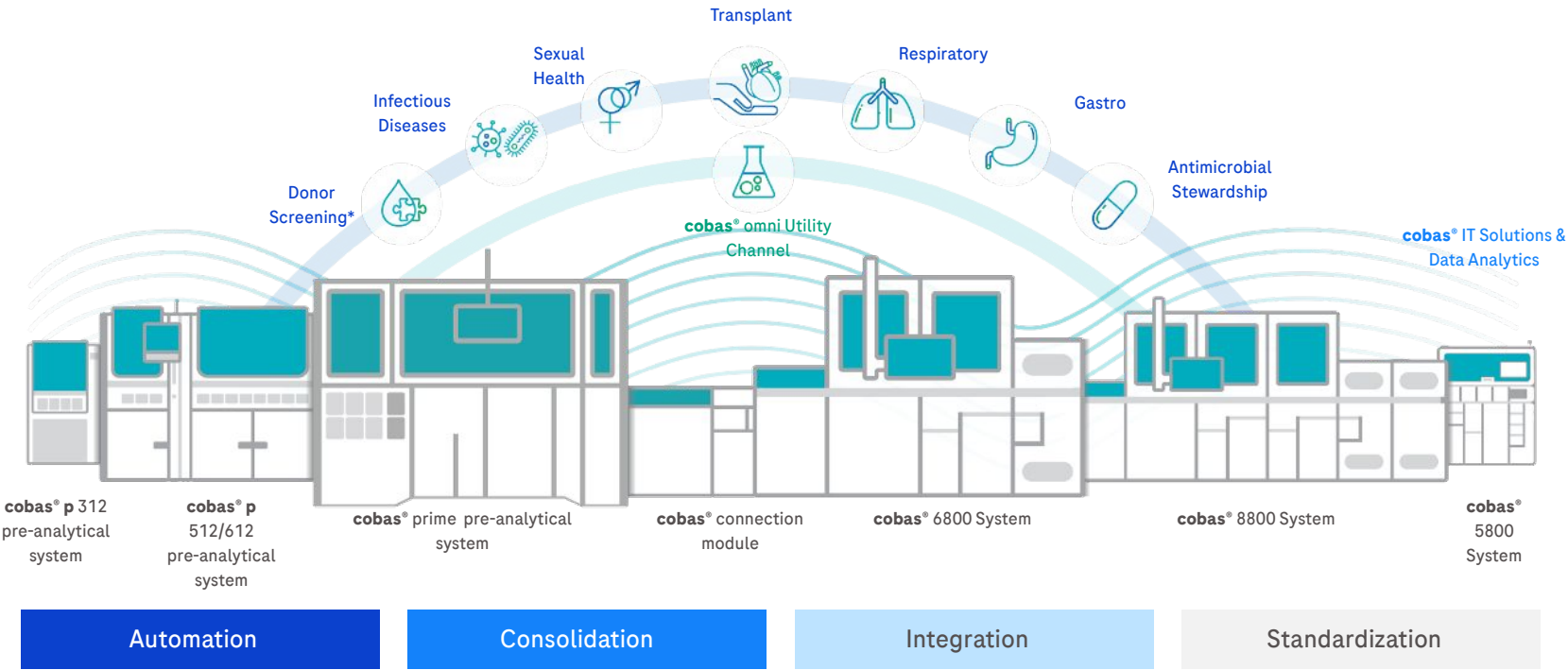
Setting-specific and patient-centered approaches expand access to molecular TB diagnostics

mWRD: molecular WHO-recommended rapid diagnostic test

Sources: Global Tuberculosis Report 2025; [Dean AS et al.](#)

Roche Commitment and Capabilities

An agile solution that can grow as your lab grows



| *When consolidated with infectious disease testing on the same cobas® 6800/8800 System

Providing integration expertise across the diagnostic continuum

We understand that integration is only possible when considerations are made at all levels

Addressing end-to-end barriers to integration



Program silos
creating duplication
& inefficiency



Disconnected data
systems



Fragmented, parallel
sample referral networks



Change of laboratory
processes

At the program level:

- All-inclusive model delivers cost-savings to all programs / entire Ministry of Health
- Template service level agreements
- Accountability through KPI monitoring and QBRs
- Workshops and tools for planning and budgeting
- Software to integrate labs into EMRs
- Technical and programmatic

At the lab network level:

- Lab optimization consultations
- Lab system strengthening trainings
- Integrated sample referral pilots and optimized network (hub-and-spoke) design
- Digitally-enabled workflow optimization
- Automated pre-analytics and inventory management
- Experience sharing: implementation guides and case studies

At the instrument level:

- Broad assay menu and multi-assay runs
- Software to ensure efficient testing schedules
- Free assay verification tool and assistance with validation studies
- **cobas®** omni Utility Channel, allows running laboratory developed tests on the same system, simultaneously with IVD assays – ideal for rapid response to outbreaks

Roche Healthcare Consultants: experienced group worldwide

300 consultants:



Certified Lean Consultants



Certified Lean Six Sigma Consultants



Change management experts



Cross-functional expertise: lab management, pathology, engineering, administration, pharmacy, biomedicine, medicine

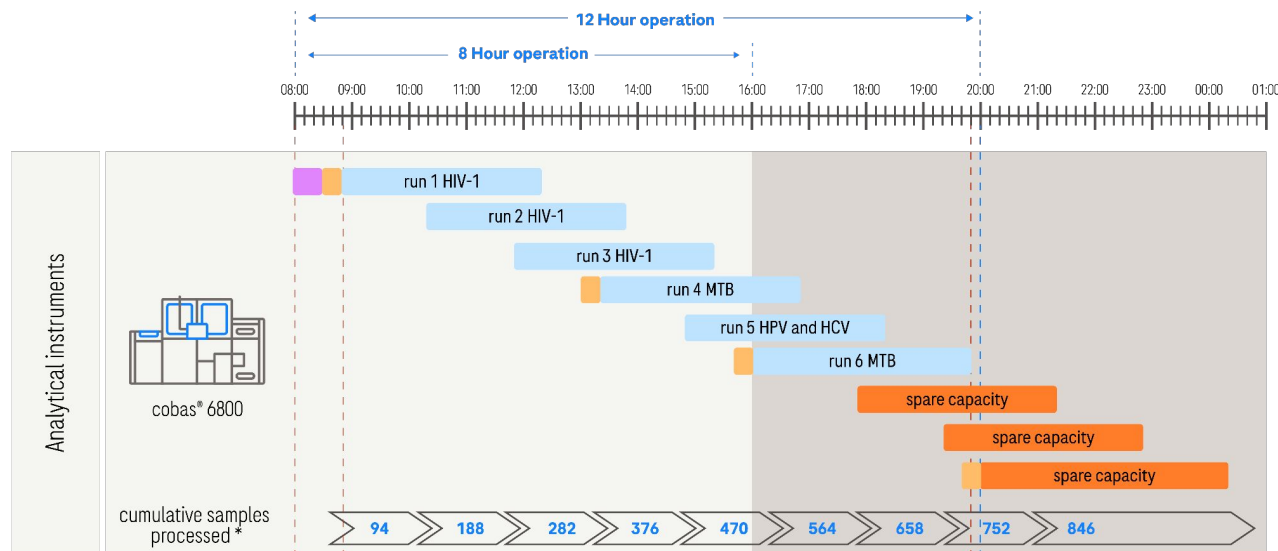


Data analysis and interpretation experts



Workflow for integrating multiple assays on a cobas 6800 System

Overview of workflow



- Weekly Maintenance (no daily maintenance)
- Load Reagents and Consumables, Empty Waste

*Assuming a full plate of a single quantitative test, requiring two controls per batch

This scenario considers a **cobas 6800** system running approx. a total of 100K tests per annum, with daily 12 hour shift.

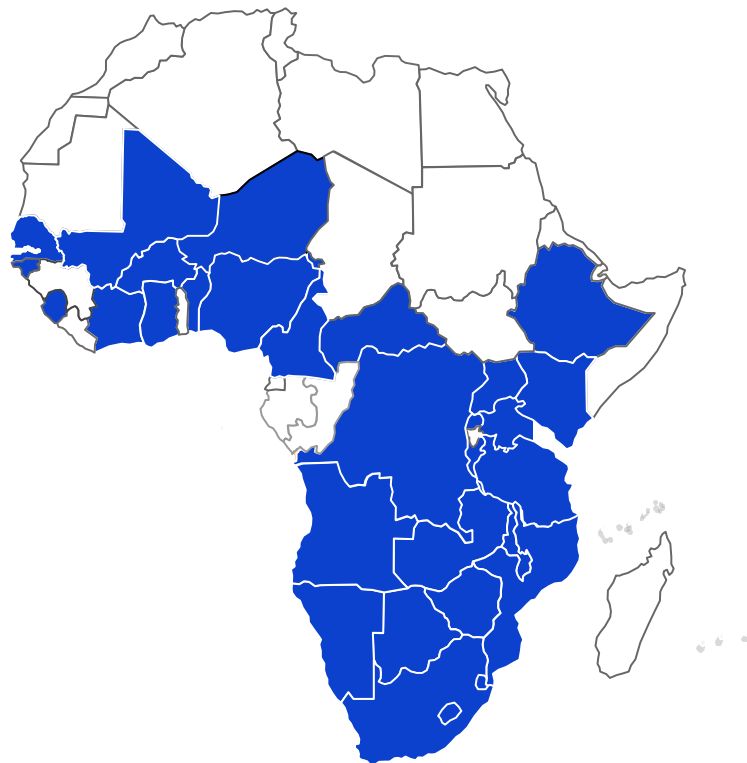
System is able to consolidate HIV, MTB, HPV and HCV and meet TATs - with an additional spare capacity.

Roche's public sector molecular footprint in Africa

Opportunity to leverage the capacity built for HIV to support other diseases

- Medium to high throughput molecular instruments across 30+ countries, put in place primarily for HIV
- Low utilization
- Spare capacity available to Laboratories

Additional tests per year to support integration, scale-up, etc.



Partnering For a TB Free Future.

Together, we can directly impact TB eradication



We follow the science

Roche has a history of providing innovative assays and remains committed to developing novel solutions for TB diagnosis.



We put patients first

Harnessing our LMIC implementation experience with clinicians and healthcare systems in 100+ countries, we focus on increasing access to high quality molecular testing for all patients, wherever they live.



We help you shape the future

We address the changing needs of National Programmes, Ministry of Health's and their citizens by partnering to shape sustainable programs, and encouraging political and financial commitments to support them.

Doing now what patients need next

Distributed by:

Roche Diagnostics (Pty) Ltd
Building E, Hertford Office Park
90 Bekker Road,
Vorna Valley,
Midrand
1686, South Africa
Tel: +27 11 504 4600

MC-ZA-02542
09/2026