



# Deploying Within Programs: Addressing implementation questions

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## Introduction

- HIV, TB, Hepatitis, HPV are leading causes of morbidity and mortality
- SARS CoV-2 has infected >480m pax
- HIV VL and EID testing is well established in Kenya



Roche C8800

## Existing HIV testing technologies have been repurposed before

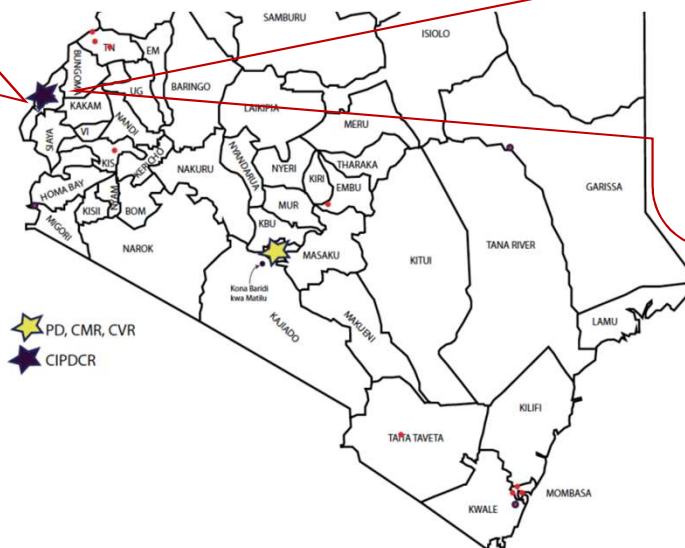
- Instruments repurposed for SARS-CoV-2 in 2020
- Hepatitis, HPV tests can be run on same platforms
- Opportunity for TB Testing
  - Diversify testing base for TB
    - increased flexibility & resilience
  - Create workflow efficiencies and cost savings
    - enhance delivery



SARS-CoV-2 Test Kits

## Snapshot of TB Testing in Kenya Today: Busia County

- Specimens collected at health facilities
- Transported to county hospital labs
- Samples Tested
- Results returned to health centers
- Patients managed



- High volume HIV testing in county lab



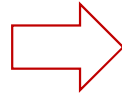
# Critical considerations

## Implementation Considerations:

## Questions to answer:

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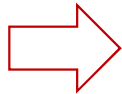
Would TB testing in the country lab change time to patient management?



What is the turn around time from patient sampling to result return to the health center today?

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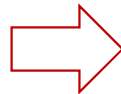
Do differentiated INH and RIF results matter for patient management?



Is mono-INH and/or mono-RIF resistance significant in the population?

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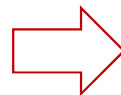
Would this be cost-neutral? Cost-saving?



What is the real-world cost of the two TB testing scenarios?

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Is it possible to integrate TB testing into the virology lab testing workflow? What do we not know?



Impact on HIV testing TAT?  
Contamination issues?

## UTILIZE Study– Using Multi-disease Testing to Enable Capacity Optimization Everywhere

Objective	Description
Workflow	<ul style="list-style-type: none"><li>• Determine the best workflow to optimize efficiencies for MTB and HIV testing on the cobas® 6800/8800 Systems</li><li>• Understand staffing requirements and volume potential to integrate MTB testing into the existing 8800 HIV testing workflow</li></ul>
Costing	<ul style="list-style-type: none"><li>• Calculate the cost per test in real-world settings for the cobas® MTB and cobas® MTB RIF/INH assays executed in the KEMRI laboratory and the Xpert MTB/RIF assay executed in county hospital laboratories</li></ul>
Epidemiology	<ul style="list-style-type: none"><li>• Collect data on the rates of RIF mono-resistant, INH mono-resistant, and MDR MTB in the Busia population.</li></ul>

## UTILIZE Study rationale

- Optimize resources to address healthcare needs via expanding diagnostic testing capabilities
- Using high volume systems that test for many pathogens increases the resilience of our labs
  - Meet current demand
  - Complement other testing capabilities
  - Flexibility to quickly respond to emerging health threats
- More data is needed in the context of real world implementation

# UTILIZE Study Population

- Will recruit patients eligible for testing based on established screening protocols (history and cough monitors).
- The current prevalence in the population is 2.5% – 5%
- Monthly volume = 600 samples
- 2000 raw sputums will be tested for MTB on the Xpert system (either at hub or from clinics).
- A minimum of 100 positives required at the cobas® MTB

Enrollment starts in April  
2022.



