

# Introduction of GeneXpert Technology in the Organisation of Eastern Caribbean States to Facilitate Tuberculosis and HIV Viral Load Testing for Key Affected Populations

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## LEARNING OBJECTIVES

By the end of my presentation, participants will be able to describe the justification and introduction of GeneXpert within the Organisation of Eastern Caribbean States (OECS) and apply the process to introduce new technologies into any laboratory.

## INTRODUCTION

Under the Global Fund OECS HIV TB Elimination Programme, a key strategy is laboratory strengthening to ensure better services to key populations. A Pan American Health Organization (PAHO) assessment of TB programmes in 2017 recommended utilization of GeneXpert technology to strengthen laboratory services in OECS countries. However, countries were not convinced of the cost-effectiveness and potential improvements.

The purpose of this intervention was to justify the adoption of GeneXpert technology within the OECS and ensure a process for its introduction that would meet Laboratory Quality Management Systems – Stepwise Improvement Process (LQMS-SIP) Tier 1 requirements for basic laboratory quality.

## CONTACT

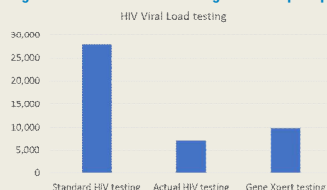
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## Programme Design

In January 2018, the OECS Principal Recipient of the Global Fund Grant and Caribbean Med Labs Foundation (CMLF) presented OECS Chief Medical Officers and Laboratory Directors with evidence illustrating that GeneXpert would provide significant cost savings and improve quality of care for TB patients. Very importantly, GeneXpert would bring capacity also for HIV viral load and many other bacterial and viral infections (e.g. chlamydia, Hepatitis C).

The process for introducing this new technology included training of laboratory staff, validating the methodology, implementing LQMS-SIP Tier 1 requirements, establishing arrangements for warranty and maintenance, and sign-off by the Ministry of Health to allocate the budget for ongoing costs.

Figure 1: Estimated Cost Savings – GeneXpert per year (US\$)



## Results and Lessons Learned

Based on the available OECS Global Fund budget, four OECS countries received GeneXpert technology. They completed the validation for TB testing with technical support from CMLF and the Caribbean Public Health Agency (CARPHA), and are now conducting their own TB testing by this method. They are currently conducting the validation for HIV viral load testing with support from the Barbados HIV Reference Laboratory.

The intervention implemented the required documentation and processes to meet Tier 1 requirements of the LQMS-SIP - including training and certification of laboratory staff, standard operating procedures, quality control and external quality assessment, equipment maintenance, etc. The OECS PR provided feedback to Ministries of Health to ensure ongoing budgetary support.

Collaboration between PAHO, OECS Commission, CARPHA and CMLF was key to the success of this intervention.

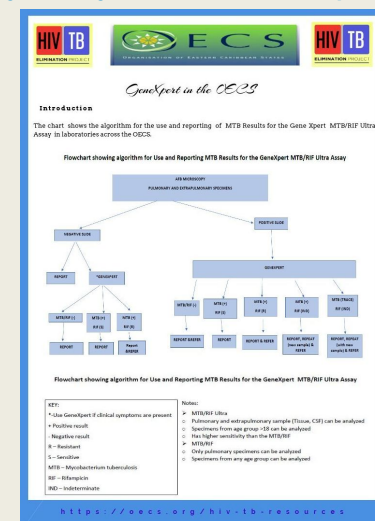
## LQMS-SIP Requirements for Introducing New Tests

- Justification for the test
- Procurement – quantities
- Inventory
- Training and competency assessment
- Internal and External Quality Control
- Verification of examination procedure
- Internal Audit
- SOP for the test – including algorithm
- Sample management (including acceptance and rejection criteria)
- Facility and environment
- External Quality Assessment (EQA)
- User Manual (including TAT)
- Equipment register, SOP and maintenance
- Calibration
- Result reporting and interpretation
- Result authorisation
- Request form (if necessary)

## Discussion

The introduction of GeneXpert in the OECS is a major advance to facilitate testing for TB and HIV viral load for key affected populations. In the process of introduction laboratory staff identified the aspects of LQMS-SIP essential for introduction of new tests into the laboratory. Participants also developed the algorithm for use of GeneXpert technology for TB diagnosis and the OECS Commission provided the finalized algorithm to clinicians, programme managers and laboratory staff to ensure that GeneXpert is integrated into TB Programme management.

Figure 2: Algorithm for Use of GeneXpert in the OECS



## Conclusions and Next Steps

The introduction of quality-assured GeneXpert technology in OECS public laboratories has the potential to radically improve care and support of persons living with HIV, infected by TB, and/or a range of viral and bacterial infections. The creation of LQMS-SIP requirements for introduction of new tests will serve as a guideline for introduction of new technologies into any laboratory.