P# 91 Implementation of SARS-CoV-2 testing at Medical Research Foundation of Trinidad and Tobago

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INTRODUCTION

The HIV Clinic at the Medical Research Foundation of Trinidad and Tobago (MRFTT) in collaboration with the Ministry of Health (MoH) supports national level diagnostic efforts by conducting HIV viral load testing using the Abbott m2000 real time polymerase chain reaction (PCR) platform installed at the MRFTT Laboratory. The MRFTT is strategically poised to scale up diagnostic PCR testing for SARS-CoV-2

In August 2020, the SARS-CoV-2 pandemic in Trinidad and Tobago was categorized as having community spread. To support the government's efforts to rapidly scale up testing and reduce the turn around time while delivering quality results, an agreement was reached with MoH to expand diagnostic testing for SARS-CoV-2 at the MRFTT laboratory.

Goals:

- 1. Support the efforts of government to rapidly scale up testing for SARS-CoV-2
- 2 Integrate SARS-CoV-2 testing at a Regional HIV Care and Treatment site.

METHODS

To introduce the new method on the Abbott m2000 PCR testing platform the first step was to determine the readiness of the MRFTT Laboratory. This was done using the WHO lab assessment tool for laboratories implementing SARS CoV-2.

The laboratory was already in the process of developing and implementing its Quality Management System (QMS) guided by the Caribbean Laboratory Quality Management System- Stepwise Implementation Process which like the readiness tool is aligned to the ISO 15189:2012 International Standard for Clinical Laboratories.

Requirements for introducing New Tests include:

- Development of a verification plan and successful completion of a verification/EQA panel
- Risk Assessment of new test
- Standard Operating Procedure for the test
- Training and competency assessment of staff
- Facilities and environment (safety and waste management)
- Instrument calibration and maintenance,
- Result reporting
- Reagent procurement and inventory





RESULTS

Achieving testing capacity while meeting the requirements of the WHO readiness tool. The following were achieved within three (3) days:

- Retraining of additional staff on Abbott Real*Time* SARS-CoV-2 assay
- Competency Assessment of all testing staff
- Detecting and eliminating an equipment maintenance non-conformity
- Ensuring all required documents were in place as listed in the method section

Providing expanding testing capacity

- Staff worked longer hours on week days to process maximum of SARS –CoV-2 while ensuring HIV VL test requests and other routine requested tests were processed
- Staff worked weekends to provide the expanded testing capacity for SARS CoV-2
- In the first 48 hours of testing >500+ were processed

The intervention encouraged the continued development and implementation of the Lab's Quality Management System. In collaboration with MoH and on successful completion of a verification panel provided by the Caribbean Public Health Agency (CARPHA) the MRFTT laboratory was able to commence COVID 19 testing on the 23rd of August 2020.

During the period August 23rd to October 14th 2020, 2057 samples were received and processed at MRFL for SARS-CoV-2..

CONCLUSION

- The introduction of an additional quality assured COVID 19 testing platform will increase capacity and reduce turn around time of results. Which will contribute significantly to the management of SARS-CoV-2 pandemic in Trinidad and Tobago.
- The additional testing platform will provide in keeping with the requirements of the International Standard "back up" in the event of equipment failure at other testing sites.
- When Trinidad and Tobago implements the COVID 19 rapid antigen tests the MRFTT can continue to support the national testing algorithm by providing confirmatory testing on the Abbott m2000 molecular testing platform.
- This expansion strengthened the MRFTT
 Laboratory services which expedited the
 development and implementation of its QMS
 and successfully integrated this new service
 in the present scope.

REFERENCES

Alemnji G, Edghill L, Guevara G, Wallace-Sankarsingh S, Albalak R, Cognat S, Nkengasong J, Gabastou JM. Development and implementation of the Caribbean Laboratory Quality Management Systems Stepwise Improvement Process (LQMS-SIP) Towards Accreditation Afr J Lab Med. 2017 Feb 24;6(1):496. doi: 10.4102/ajlm.v6i1.496.

Degli-Angeli E, Dragavon J, Huang ML, Lucic D, Cloherty G, Jerome KR, Greninger AL, Coombs RW. Validation and verification of the Abbott RealTime SARS-CoV-2 assay analytical and clinical performance .J Clin Virol. 2020 Aug;129:104474. doi: 10.1016/j.jcv.2020.104474.

Mitchell SL, St George K, Rhoads DD, Butler-Wu SM, Dharmarha V, McNult P, Miller MB. J. Understanding, Verifying, and Implementing Emergency Use Authorization Molecular Diagnostics for the Detection of SARS-CoV-2 RNA. Clin Microbiol. 2020 Jul 23;58(8):e00796-20. doi: 10.1128/JCM.00796-20.

Ravi N, Cortade DL, Ng E, Wang SX. Diagnostics for SARS-CoV-2 detection: A comprehensive review of the FDA-EUA COVID-19 testing landscape. Biosens Bioelectron. 2020 Oct 1;165:112454. doi: 10.1016/j.bios.2020.112454.