Equipping laboratories for performing robust evaluations of COVID-19 diagnostics under emergency use authorisation: lessons learnt from South Africa

ASLM2021 Satellite Session

Sponsor
University of the Witwatersrand and National Health Laboratory Service

Date and Time
16 November 2021, 7AM-8AM GMT

Summary
South Africa reported their first COVID-19 case in March 2020, but access to relevant diagnostics was limited in spite of a large laboratory footprint in place to support their HIV and tuberculosis national diagnostic program. Delays in international diagnostic evaluation guidelines and performance acceptance criteria and challenges in performing clinical evaluations meant the laboratory had to play a central role in rapid evaluation of accessible diagnostics, and assist local developers who are unable to access regulatory bodies. The Department of Molecular Medicine and Haematology (University of the Witwatersrand, Johannesburg), in collaboration with the National Health Laboratory Service, therefore developed protocols and processes to rapidly evaluate relevant COVID-19 diagnostics in readiness for scaled implementation and in-country regulation. The entire pathology value chain must be considered when selecting suitable diagnostic assays, with each step contributing to meaningful and valid test results: specimen collection; specimen handling and storage; specimen testing (POC and central laboratory), viral RNA purification, amplification and detection (for nucleic acid amplification technology (NAAT)); and result interpretation. Work streams developed through extensive experience in HIV and TB diagnostic evaluations were re-purposed for COVID-19. Landscape reviews were conducted and >150 assays were evaluated. These included (1) NAAT which detects viral RNA; (2) antigen tests which target viral proteins and are an alternative option to rapidly detect active infections at point of care (POC); and (3) serology tests which detect antibodies developed in response to the virus, including formal laboratory based assays and POC rapid lateral flow and chemiluminescent immunoassays. The most recent evaluation work stream addresses the potential impact of emerging SARS-CoV-2 variants on diagnostics. Extensive knowledge and experience has been gained and we share challenges, complexities and innovative ways to rapidly evaluate relevant diagnostics from an ever expanding development pipeline, as well as insights into scaled implementation post-evaluation during country lock-down.

Learning Objectives

This session aims to communicate the experiences gained from validating diagnostic assays in the midst of the COVID-19 pandemic and the development of robust protocols for evaluation in the absence of costly clinical trials. The speakers will highlight the challenges and complexities that were faced, as well as the success achieved in developing a robust validation system that has contributed to the readiness of national diagnostic laboratories. This is a holistic approach that covers the range of testing technologies used for SARS-CoV-2 diagnostics including issues of emerging variants. The real-world diagnostic experience will showcase the current situation in South Africa.

Target Audience

The target audience for this session are members of the scientific and medical community, technology regulators and implementation decision makers to provide insights to better understand assay evaluation complexities and performance criteria. Members from industry (e.g. developers of new diagnostic assays) may also find the session valuable.

Session Programme

Presenter & Affiliation	Title
Prof. Wendy Stevens University of the Witwatersrand and National Health Laboratory Service	National Laboratory systems: South African response to COVID-19
Prof. Lesley Scott University of the Witwatersrand	Determining work streams for laboratory preparedness in evaluating COVID-19 diagnostics under emergency use authorisation
Prof. Elizabeth Mayne University of the Witwatersrand and National Health Laboratory Service	Evaluating serology diagnostics under emergency use authorization and determining performance criteria
Mrs. Lara Noble University of the Witwatersrand	Evaluating SARS-CoV-2 molecular diagnostics under emergency use authorization and determining performance criteria
Dr. Vidya Keshav University of the Witwatersrand	Evaluating SARS-CoV-2 rapid diagnostics under emergency use authorization and determining performance criteria
Dr. Marvin Hsiao National Health Laboratory Service	Determining the impact of SARS-CoV-2 variants on diagnostics
Dr. Lucia Hans National Health Laboratory Service	Challenges for implementation of technologies post validation