Bureau International des Poids et Mesures

CCQM

CCQM Webinar on 'Ensuring the reliability of measurements in response to the COVID-19 pandemic'

7 July 2020 at 14h00 (UTC+2)

For the first of a series of CCQM Webinars dedicated to the reliability of measurements in response to the COVID-19 pandemic we have four invited presentations from external experts on the needs and their activities in addressing the reliability of molecular diagnostic and antibody tests for Covid-19. The webinar is designed to inform National Metrology Institutes on areas where measurement science can respond to the challenges in ensuring reliability and performance of test kits.

Organizing Committee: J. Huggett (LGC), J. Melanson (NRC), B. Güttler (PTB), G. O'Connor (PTB), J. Campbell (LGC), R. Wielgosz (BIPM), S-R. Park (CIPM).

Webinar schedule

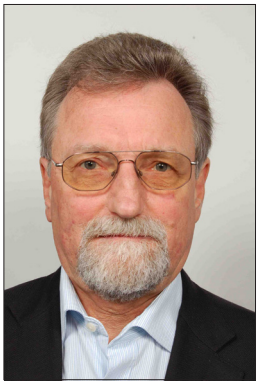
- 14:00-14:05 Webinar structure and guidance for panelists and attendees, R. Wielgosz
- 14:00-14:10 Introduction to Webinar form CCQM NAWG and PAWG Chairs, J. Huggett and J. Melanson
- 14:10-14:30 COVID-19 Diagnostics: from measurement to policy, J. Moran-Gilad
- 14:30-14:35 Questions
- 14:35-14:55 Molecular Diagnostics: International proficiency testing as basis for standardizing genome detection of SARS-CoV-2, H. Zeichhardt
- 14:55-15:00 Questions
- 15:00-15:20 SARS-CoV-2 Antibody testing and the challenges in standardization of measurements: What we can learn from interlaboratory studies and what are the implications? M. Neumaier
- 15:20-15:25 Questions
- 15:25-15:45 The Development and Assessment of Covid-19 Serological Platforms for Serosurveillance and Potential Immunity Correlation, M. A. Drebot
- 15:45-15:50 Questions

COVID-19 Diagnostics: from measurement to policy
Prof. Jacob Moran-Gilad

This talk will review the different diagnostic modalities involved in the response to the COVID-19 pandemic, such as molecular, serological and sequence-based assays. The potential applications of diagnostics assays in the management of the pandemic will be discussed along with analysis of gaps and challenges related to the analytical and diagnostic performance of these technologies and lessons learnt.

Prof. Jacob Moran-Gilad is a physician board-certified in clinical microbiology and in public health. Prof. Moran-Gilad is the PI of the Microbiology, Advanced Genomics and Infection Control Applications Laboratory (MAGICAL group) at the Ben Gurion University of the Negev and consultant microbiologist at the Soroka University Medical Center Beer Sheva, Israel and Director of Clinical Microbiology at the Hadassah Medical Center, Jerusalem, Israel, and Programme Director for the European Congress on Clinical Microbiology and Infectious Diseases (ECCMID).

Molecular Diagnostics: International proficiency testing as basis for standardizing genome detection of SARS-CoV-2
Prof. Dr. Heinz Zeichhardt



The results of the international proficiency testing scheme of April 2020 for molecular diagnostics for SARS-CoV-2 run by INSTAND e.V. are presented. 463 laboratories from 36 countries submitted results. Regardless of the gene region tested, the genome detection tests for SARS-CoV-2 generally revealed correct results both for positive and negative samples. The EQA scheme also covered quantitative results reported in copies/ml, obtained by reverse transcription quantitative PCR (RT-qPCR) as well as reverse transcription digital PCR (RT-dPCR). Values from RT-qPCR showed considerable variation which might have been due to the absence of an international reference material necessary for calibration. However, the results from RT-dPCR, which as a limiting dilution method has the potential to be applied without a calibrator, revealed only slight variations. The use of RT-dPCR for assigning reference measurement values on reference materials for the determination of the limit of detection of a genome tests for SARS-CoV-2 and as an anchor material for routine diagnostics will be discussed. The application of dPCR for quantification of the genomes of both DNA and RNA viruses, such as cytomegalovirus and HIV-1, has already proven successful for virus load detection in the context of therapy monitoring.

Prof. Dr. Heinz Zeichhardt is CEO and Scientific Director of the Gesellschaft fuer Biotechnologische Diagnostik mbH, Berlin, and the IQVD GmbH, Berlin, and previously Professor of Virology at Charité – University Medicine Berlin, Institute of Virology, CBF. He is an expert for quality management in laboratory medicine and organizer of INSTAND and WHO external quality assessment schemes in virus diagnostics.

SARS-CoV-2 Antibody testing and the challenges in standardization of measurements: What we can learn from interlaboratory studies and what are the implications?
Prof. Michael Neumaier

Testing for antibodies against SARS-CoV-2 provides a considerable measurement and standardization challenge. Standardization issues include consideration of the SARS-CoV-2 antigens to be tested for. Most tests use the Spike protein, the RBD thereof or the Nucleocapsid protein of the 25-29 proteins suspected to be coded for by the virus. With the extensive molecular evolution of the virus, an important standardization issue is to define epitopes common to virus derivatives that are also sufficiently immunogenic. External quality assurance (EQA) is an important instrument to compare the results of antibody test systems as a first step towards standardization/ harmonization. However, EQA programmes need to be more extensive in order to verify test performances of the laboratories.

Prof. Michael Neumaier is Vice Dean of the Medical Faculty Mannheim of the University Heidelberg and member of the EB of the University Medicine Centre Mannheim, and currently holds the position of Past President of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM). He is Director of the German national “External Quality Assessment in Laboratory Medicine” program, a member of the Advisory Board of German Medical Council and Chairman of the Expert Panel group on Molecular Diagnostics of the German Medical Council.

The Development and Assessment of Covid-19 Serological Platforms for Serosurveillance and Potential Immunity Correlation
Dr Michael A. Drebot

During this presentation a number of serological platforms for detection of Covid-19 virus antibody will be described including lateral flow cassettes, ELISAs, and neutralization assays. For validation purposes and determination of performance characteristics a key component for serology test development is the reference panel used to assess individual kits or test formats. Not all panels are “created equal” and considerations for the makeup of a particular reference panel will be discussed and how heterogeneity of serum / plasma samples may influence sensitivity and specificity parameters with respect to serological assays. Experimental findings summarizing data obtained during the assessment of a variety of serological platforms will be presented.

Dr Michael Drebot is the Director of the Zoonotic Diseases and Special Pathogens (ZDSP) division at the National Microbiology Laboratory, Winnipeg and an Associate professor within the Medical Microbiology and Infectious Diseases Department, University of Manitoba. Recently Dr. Drebot and his ZDSP scientists have been involved with the evaluation of commercial serological kits for the detection of antibodies to the Covid-19 virus. He is a member of the CPHLN Covid-19 Serology Task Force and provides consultation to various working groups associated with the Covid-19 National Immunity Task Force.