Advancing SARS-CoV-2 Virus Testing During the Global Emergency

Presentation to Coronavirus Standards Working Group
Russell Garlick, LGC SeraCare Life Sciences
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Status

• National emergencies declared to diagnose and treat COVID-19
• FDA declared Emergency Use Authorizations guidelines effective Feb 4th
  FDA is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency.
  48 manufacturers
  25 LDTs
• NP and OP collection and SARS-CoV-2 viral assays are central to standard of care to diagnose symptomatic COVID-19 disease
• Multiple formats, changing throughput requirements and multiple specifications have yielded a wide variation of performance
• Laboratories around the world continue to ramp up and need direction
• Coronavirus Working Group establish to:
  • Inventory of assays, materials and gap analysis
  • publish principles of assay standardization and best practices to assess measurement bias etc.,
  • Design and develop standards, interlab study
  • Infrastructure
Emergency Use Authorizations as of May 6th

- 48 Manufactures

- 25 LDTs
  UTMG Pathology Laboratory, Altru Diagnostics, Inc., Biocerna, Nationwide Children's Hospital, Ultimate Dx Laboratory, AIT Laboratories, Southwest Regional PCR Laboratory LLC. dba MicroGen DX, Diatherix Eurofins Laboratory, Mayo Clinic Laboratories, Rochester, MN, Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory, CirrusDx Laboratories, Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital, Exact Sciences Laboratories, Integrity Laboratories, Pathology/Laboratory Medicine Lab of Baptist Hospital Miami, Orig3n, Inc., Rutgers Clinical Genomics Laboratory-Rutgers University, Specialty Diagnostic (SDI) Laboratories, University of North Carolina Medical Center, Stanford Health Care Clinical Virology Laboratory, Viracor Eurofins Clinical Diagnostics, Massachusetts General Hospital, Diagnostic Molecular Laboratory – Northwestern Medicine, Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia, Yale New Haven Hospital, Clinical Virology Laboratory
What immediate need can the Coronavirus Working Group Address?

• Evaluate and inform on EUA testing
  • Evaluate performance of all EUA SARS-CoV-2 Viral assays (49 manufacturers, 25 LDTs),
    • Requires incentives or a catalysts for all EUA to participate
  • Results will inform assay requirements for the NextGen assays during this public health crisis
  • Global involvement

• Must not replace or overlap with standard CLIA certifications or EQA/PT testing schemes already in place (1,000s of labs)

• For our working group, combine design and testing of standards with interlab study into one project needed today
Project Scheme – Time Sensitive - Global

Design Ref Mat & Recruit EUA participants

• Workflow assessment
• Intended use statement
• Inactivated or recombinant virus
• VTM, saliva
• Copies / test

Manufacture & assign values

• Scale up, stability
• Multiple assay formats
• Statistical plan
• Assigning “truth”

Distribute “test panel” & assay

• Coordinated distribution and testing
• EUA manufactures and EUA LDTs test RMs

Evaluate & report

• Data returned to working group for analysis
• Results informs performance of EUA
Recommendation

• Establish a smaller working team to develop the concept further and report back to CSWG next Friday
  
  • Intended use statement
  
  • Expand on the Project Scheme

• Discussion and next steps