Coronavirus Standards Working Group

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

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- 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

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- 48 Manufactures

Centers for Disease Control and Prevention's (CDC), Wadsworth Center, New York State Department of Public Health's (CDC), Roche Molecular Systems, Inc. (RMS), Thermo Fisher Scientific, Inc., Laboratory Corporation of America (LabCorp), Hologic, Inc., Quest Diagnostics Infectious Disease, Inc., Quidel Corporation, Abbott Molecular, GenMark Diagnostics, Inc., DiaSorin Molecular LLC, Cepheid, Primerdesign Ltd., Mesa Biotech Inc., BioFire Defense, LLC, PerkinElmer, Inc., Avellino Lab USA, Inc., BGI Genomics Co. Ltd, Luminex Molecular Diagnostics, Inc., Abbott Diagnostics Scarborough, Inc., QIAGEN GmbH, NeuMoDx Molecular, Inc., Ipsum Diagnostics, LLC, Becton, Dickinson & Company (BD), Co-Diagnostics, Inc., ScienCell Research Laboratories, Luminex Corporation, Gnomegen LLC, InBios International, Inc, DiaCarta, Inc, Becton, Dickinson & Company, Atila BioSystems, Inc., Maccura Biotechnology (USA) LLC, KorvaLabs Inc., GenoSensor, LLC, Fosun Pharma USA Inc., OSANG Healthcare, Trax Management Services Inc., Seegene, Inc., altona Diagnostics GmbH, SD Biosensor, Inc., SEASUN BIOMATERIALS, LabGenomics Co., Ltd., Rheonix, Inc., Bio-Rad Laboratories, Inc, BioFire Diagnostics, LLC, Sansure BioTech Inc., Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)

- 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?

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- 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, <u>combine design and testing of standards with interlab study into one project needed today</u>

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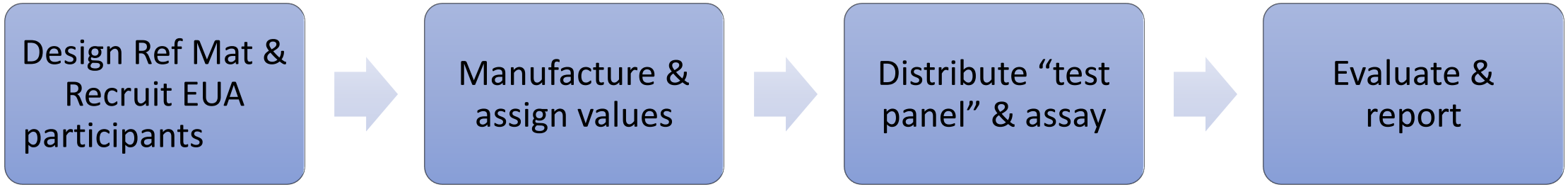
Project Scheme – Time Sensitive - Global



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

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

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

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

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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