SARS-CoV-2 Serological Standards Harmonization

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Coronavirus Standards Working Group
What should a Coronavirus Standards Working Group do?

- Assure development and availability of standards, controls, interlab testing, knowledge to support successful rollout & scaling of 2019-nCoV testing
- Identify and develop critical infrastructure to support...
  - confidence in test results
  - interoperability
  - scale-up
  - long-term capacity
- Identify best practices that should be institutionalized
  - Learn what we need to do next time we have a global network in place ready to make standards.
Objectives

▸ To align multiple SARS-CoV-2 serology reference materials with the 20/136 WHO International Standard.

▸ Allow global accessibility to quality materials to calibrate their serology tests.

▸ Improve the equity of access to SARS-CoV-2 Serology reference materials.
What this Study **will not** do

- Compare serology testing
- Rank current reference materials
- Compare performance between labs
- Evaluate performance of serology testing
Material & Lab Recruitment

01 Candidate Serology
Material Attributes

02 Candidate Testing Lab
Attributes

Type of Source Material
Antibody Contents
Handling Requirements (DTS, neat, lyophilized, etc.)
Storage/Shipping Temperature
Infectious disease testing performed on material

Test Method,
Manufacturer
Lab source (clinical, academic, reference, etc.)
Antigen Target used (S, RBD, N, whole virus, etc.)
Antibody type detected (IgM, IgG, IgA, Total Ig, etc.)
Candidate Lab Focus Areas

- Tests that offer measures that are correlates of protection (vaccine performance)
  - Neutralization, ELISA, etc.

- Tests deployed for serosurveillance in low resource settings.
  - RDTs, Lateral Flow, etc.
Between 5-10 well-characterized validated samples (panels or individual samples)

3 Clinical Labs

3 Academic Labs

1 Reference or Standards Lab

1-5 Methods Each

All results run in triplicate

WHO 20/136 IS

Calibration & International Unit Conversion
Teams are built
- Teams will convene internally
- Report on progress during Friday meetings

End of March 2021

Finalization of materials & Distribution
- Teams share final products
- Materials are all shipped to each lab on the same week

Mid-April 2021

Labs begin to report data
- Use harmonized SOP for material management & testing.
- Report data in centralized REDCap form
- Note any issues with materials, testing, shipments, or storage.

May 2021

Data analysis
- Data are aggregated and analyzed
- Materials calibrated to WHO International Standard 20\136
- Publish Findings
Who wants to help?

01 Materials recruitment
- Identify labs to supply reference materials
- Design the combined panel
- Compile sample handling & integrity information

02 Lab coordination
- Recruit/mobilize testing labs
- Compose harmonized SOP for sample handling
- Evaluate import & shipping needs

03 Data reporting
- Design harmonized reporting form
- Store & archive data reports

04 Analysis
- Design analysis strategy
- Calibrate panels to WHO International Standard 20/136
- Analyze findings
Discussion