SARS-CoV-2 Serological Standards Harmonization

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Coronavirus Standards Working Group

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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

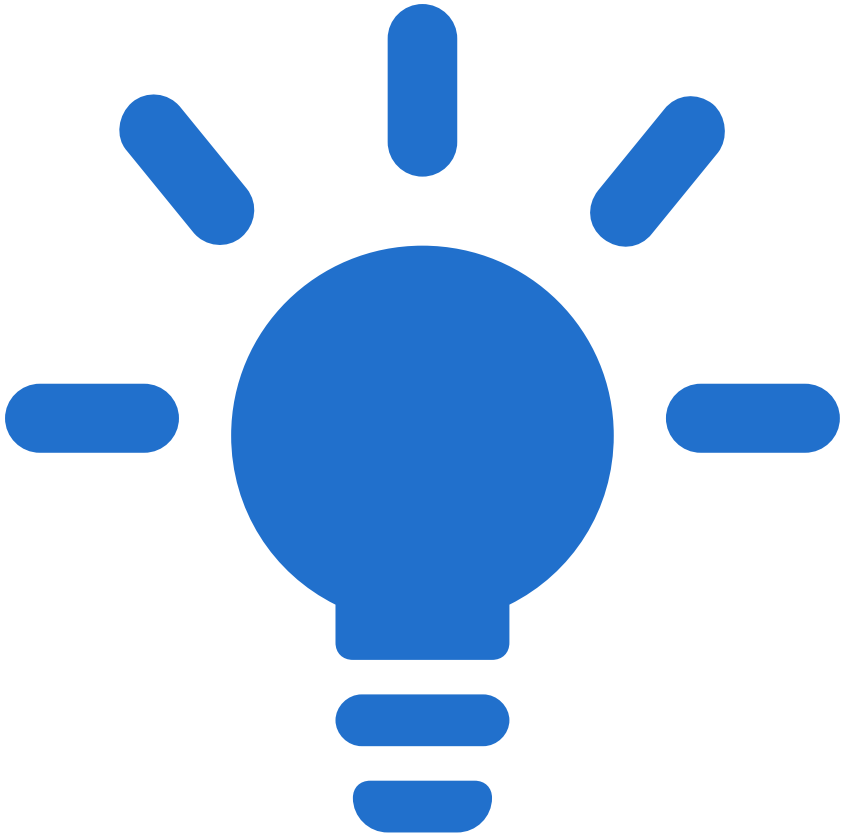
Learn what we need to so next time we have a global network in place ready to make standards.

SARS-CoV-2 Serology Reference Material Harmonization

By: Marc Salit, PhD; May Chu, PhD & Jon Windsor, MLS (ASCP), MPH

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

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

02

Candidate Testing Lab Attributes

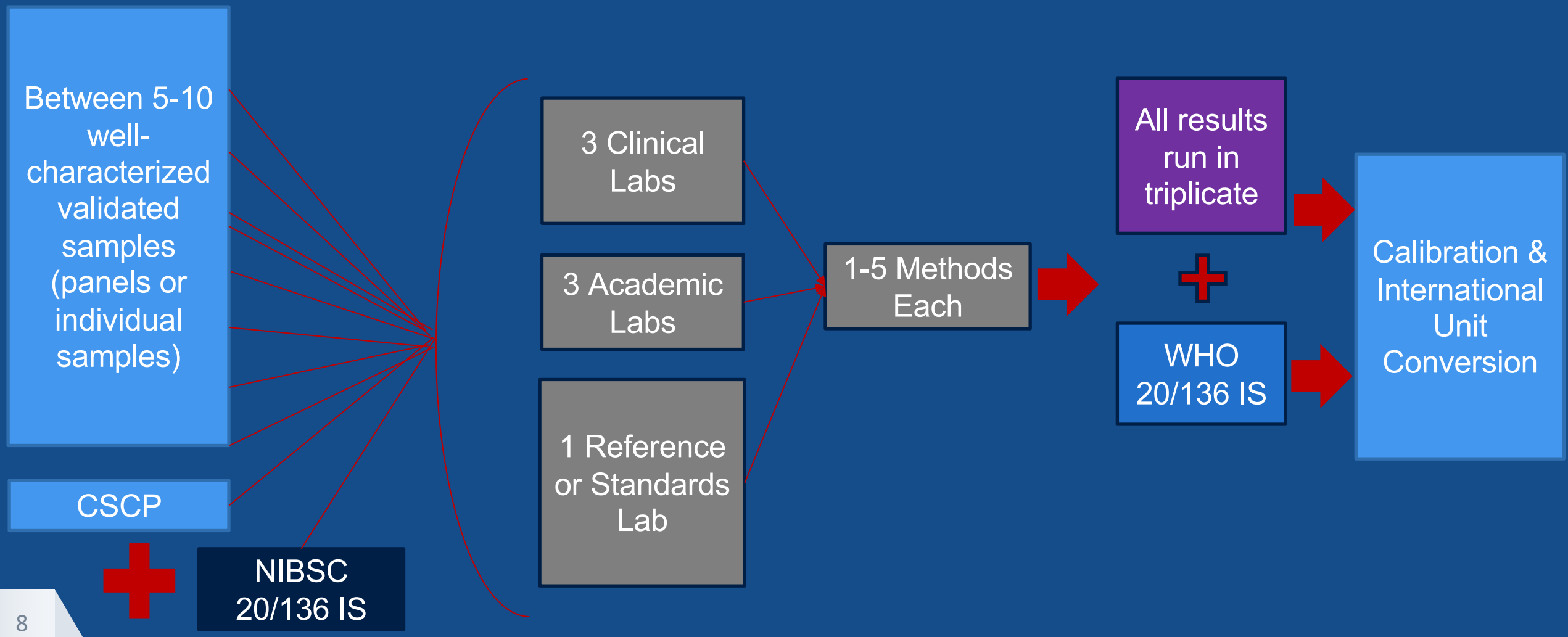
Test Method,
Manufacturer
Lab source (clinical, academic, reference, etc.)
Antigen Target used (S, RBD, N, whole virus, etc.)
Antibody type detected (IgM, IgG, IgA, Total Ig, etc.)

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.

Study Design



Timeline

Teams are built

- Teams will convene internally
- Report on progress during Friday meetings

February 2021

End of March 2021

Finalization of materials & Distribution

- Teams share final products
- Materials are all shipped to each lab on the same week

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.

Mid-April 2021

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