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 so next time we have a global network in place ready to make standards.
SARS-CoV-2 Serological Standards

• May has been involved with the WHO COVID-19 Advisory Committee on Infection Prevention and Control as well as been engaged through Gates Foundation on quality and performance of SARS-CoV-2 serological assays.

• May and Jon lead the effort on the COVID-19 Serology Control Panel and will offer a vision to follow up the molecular Harmonization Study with a similar harmonization for serology samples.
Proposal – mimic CSWG RNA Standards Harmonization Study

Calibrate to WHO International Standard

Multiple materials

Multiple labs

Designed Experiment

World Health Organization

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva, 9 - 10 December 2020

Establishment of the WHO International Standard and Reference Panel for anti-SARS-CoV-2 antibody

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* Listed in Annex 1

NOTE:
This document has been prepared for the purposes of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS). Comments MUST be received by 3 December 2020 and should be addressed to the World Health Organization, 1211 Geneva 27, Switzerland, attention: Technologies, Standards and Specifications (TS&S). Comments may also be submitted electronically to the Responsible Officer: Dr Franz Kasner at email: franz.kasner@who.int
Purpose

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
Study Design

- Ref panel 1
- Ref panel 2
- Ref panel 3
- Ref panel 4
- Ref panel 5
- Ref panel 6
- Ref panel 7
- Ref panel 8
- Ref panel 9

- Lab 1
- Lab 2
- Lab 3
- Lab 4
- Lab 5
- Lab 6
- Lab 7
- Lab 8
- Lab 9

1-5 Methods Each

All results

WHO 20/136 IS

Calibration & International Unit Conversion

NIBSC 20/136 IS
Logistical Considerations

- Representation of different methods
  - Neutralization, Lateral Flow, ELISA, etc.

- Representation of labs sharing materials
  - Should not be limited to US & UK

- Shipping limitations
  - Will the materials arrive in a timely manner
  - Import permit considerations

- Variability between labs

- Integrity of materials
  - Will each panel require slightly different shipping/storage conditions?
# Teams and Milestones

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| **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 |
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 packaged at UoC & sent to labs

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
Discussion