12 February 2021

Marc Salit,
JIMB Director

SLAC National Lab
Stanford University

SARS-CoV-2 Serological Standards Harmonization

May Chu & Jon Windsor
Center of Global Health at the
Colorado School of Public Health

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

WHO/BS/2020.2403
ENGLISH ONLY

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

Giada Mattiuzzo[1]# , Emma M. Bentley[1], Mark Hassall[1], Stephanie Routley[1], Samuel Richardson[1], Valentina Bernasconi[2], Paul Kristiansen[2], Heli Harvala[3], David Roberts[3], Malcom G Semple[4] , Lance CW Turtle[4], Peter JM Openshaw[5] and Kenneth Baillie[6] on behalf of the ISARIC4C Investigators, Lise Sofie Haug Nissen-Meyer[7], Arne Broch Brantsæter[8], Helen Baxendale[9], Eleanor Atkinson[10], Peter Rigsby[10], David Padley[11], Neil Almond[11], Nicola J. Rose[1], Mark Page[1] and the collaborative study participants*

[1]Division of Virology, National Institute for Biological Standards and Control, UK;[2]Coalition for Epidemic Preparedness Innovations, Norway; [3]National Health Service Blood and Transplant, UK;[4] University of Liverpool, UK; [5]National Heart and Lung Institute, Imperial College London, UK, [6]Roslin Institute, University of Edinburgh, UK; [7]Department of Immunology and transfusion Medicine and [8]Department of Infectious Diseases and Department of Acute Medicine, Oslo University Hospital, Norway;[9]Royal Papworth Hospital NHS Foundation Trust; [10]Statistics group and [11]Division of Infectious Disease Diagnostics, National Institute for Biological Standards and Control, UK

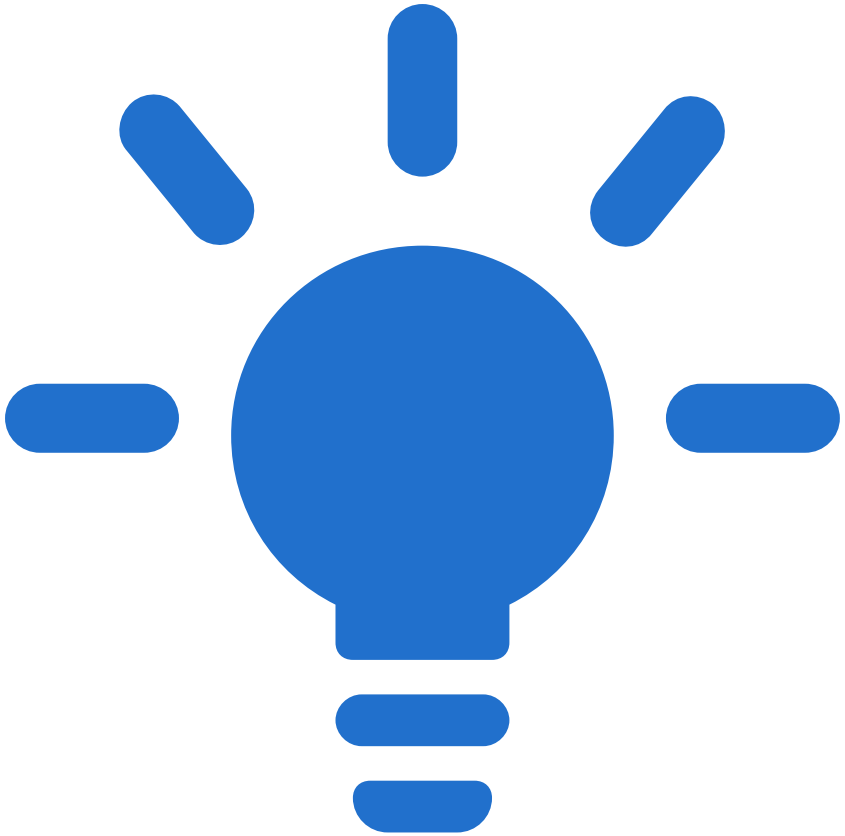
#Study coordinator: TEL:+44 1707641283, E-mail: Giada.Mattiuzzo@nibsc.org
*listed in Annex 1

NOTE:
This document has been prepared for the purpose 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 (TSS). Comments may also be submitted electronically to the Responsible Officer: **Dr Ivana Knezevic** at email: knezevici@who.int.

SARS-CoV-2 Serology Reference Material Harmonization

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

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

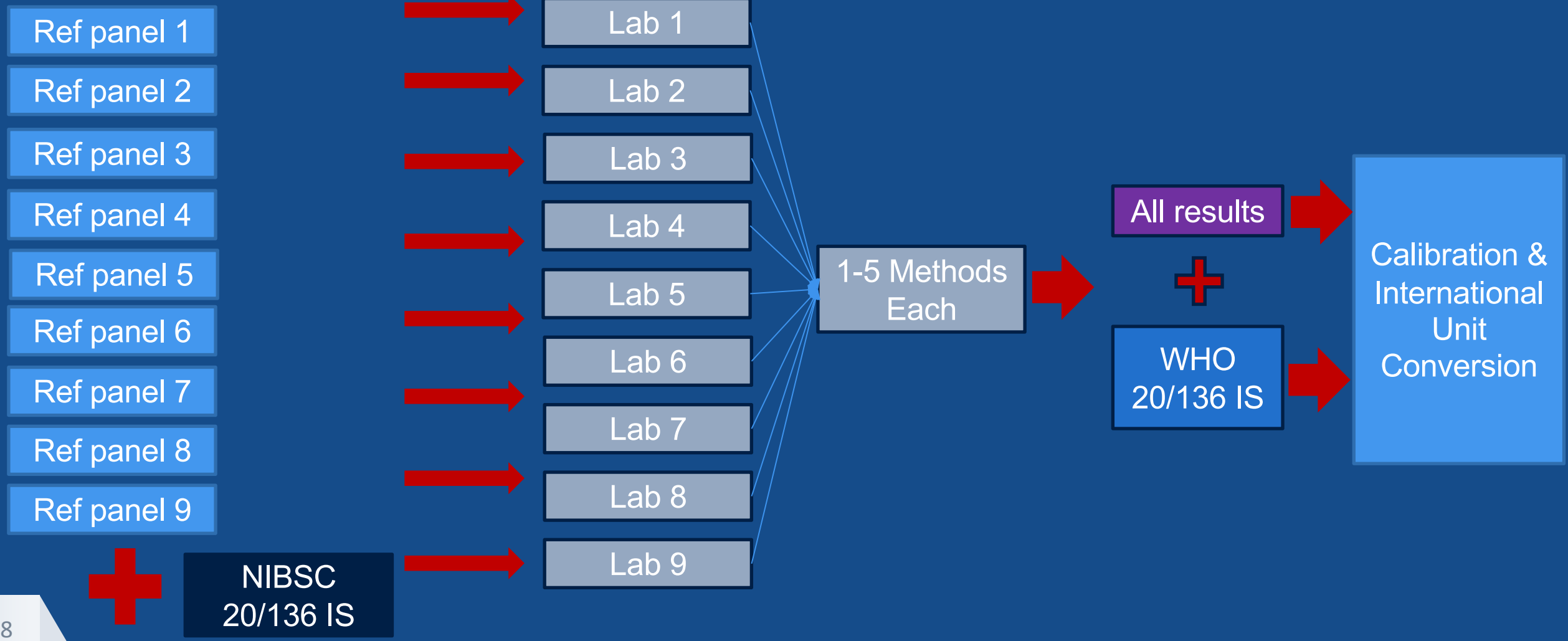
Compare serology testing

Rank current reference materials

Compare performance between labs

Evaluate performance of serology testing

Study Design



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

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

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.

February 2021

End of March 2021

Mid-April 2021

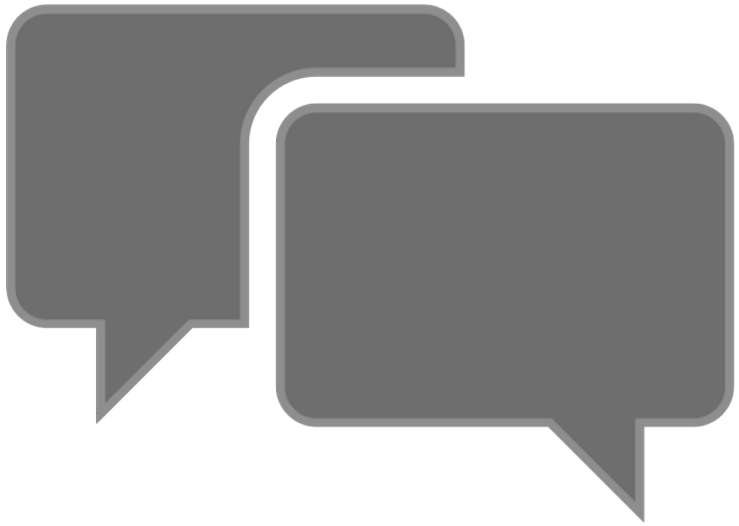
May 2021

Finalization of materials & Distribution

- Teams share final products
- Materials are packaged at UoC & sent to labs.

Data analysis

- Data are aggregated and analyzed
- Materials calibrated to WHO International Standard 20\136



Discussion