

12 March 2021

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Creating the WHO Antibody Reference Panel

Mark Page, NIBSC

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.

Agenda



Updates



Creating the WHO
Antibody Reference
Panel

Mark Page

Updates

Viral RNA Standards Harmonization Study

- Panels Shipped!
- Details following

Serology Standards Harmonization Study

- May Chu and team at Colorado School of Public Health Anschutz Medical Center leading development
- Requests being sent out to develop panel of materials
- Design and planning underway

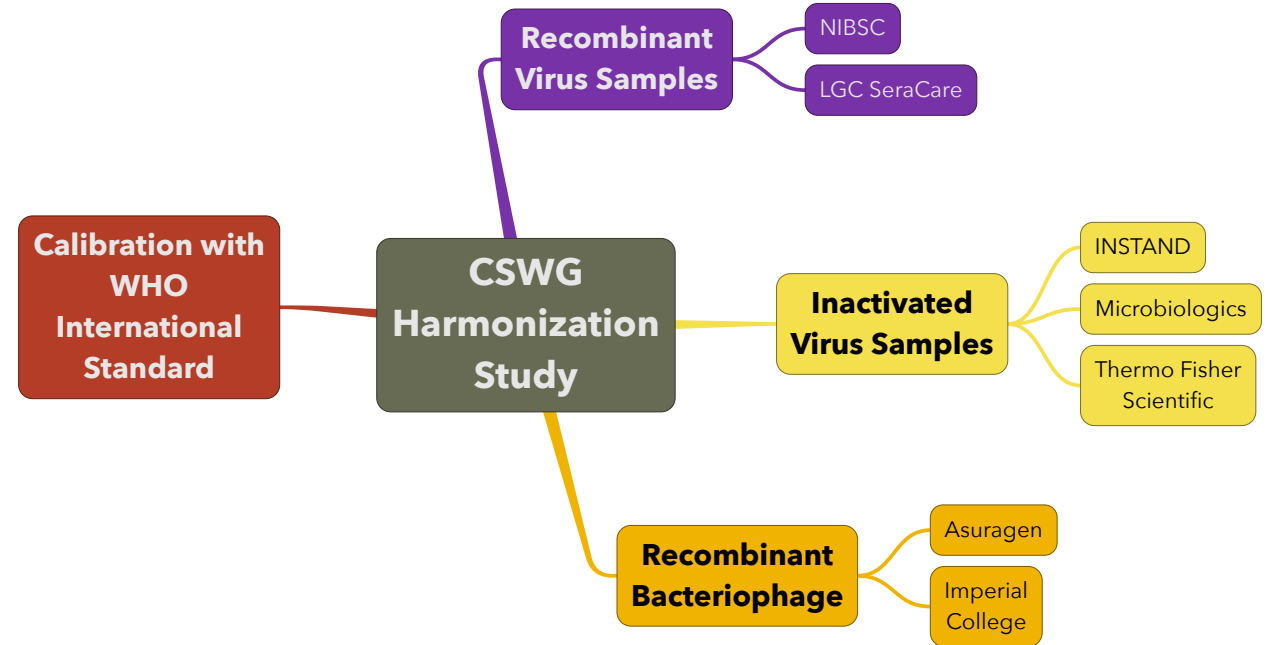
Viral RNA Harmonization Study

Samples received at 12/14 labs as of 11 March

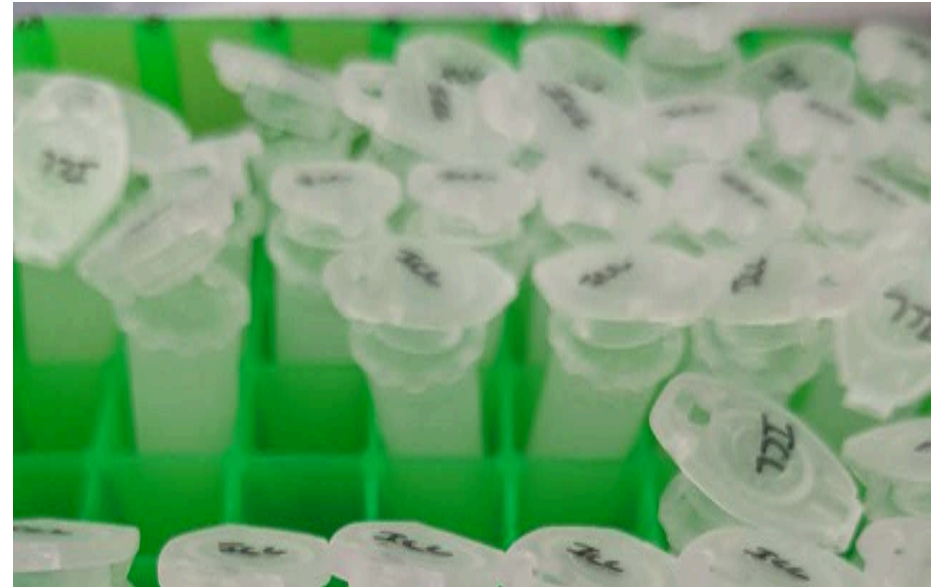
- One package mis-shipped
- One package in transit



Zeptomatrix
sample not
included in
panel



Imperial College samples packaging failure



- Rescued and shipped in outer "Falcon" tube
 - might consider as provisional results; samples can be excluded at lab discretion



Results reporting template distributed

CSWG: Viral RNA Harmonization Study Data Reporting Template ★ 🗑️ ☁️

File Edit View Insert Format Data Tools Add-ons Help Last edit was 1 hour ago

100% | \$ % .0 .00 123 | Arial | 12 | **B** *I* U A | 📌 🏠 📄

	A	B	C	D	E	F	G
1	Sample code	Sample name	Replicate_1	Replicate_2	Replicate_3	Replicate_4	
2	ISN	WHO-IS_neat					
3	IS1	WHO-IS_dilution_1					
4	IS2	WHO-IS_dilution_2					
5	IS3	WHO-IS_dilution_3					
6	IS4	WHO-IS_dilution_4					
7	IS5	WHO-IS_dilution_5					
8	IS6	WHO-IS_dilution_6					
9	I1	Instand					
10	I2	Microbiologics					
11	I3	Thermo Fisher					
12	R1	LGC SeraCare					
13	R2	NIBSC					
14	P1	Asuragen					
15	P2	Imperial College					
16	NTC	Nontemplate_control					
17							
18							
19							
20							
21							
22							
23							

+ ☰ Target 1 ▾ Target 2 ▾ Target 3 ▾ Target 4 ▾ Batch structure (if any) ▾

Sample manifest distributed

CSWG Shipping Manifest

Supplied Reagents: Each lab will receive 4 vials of each of the following:

Instand

Catalogue no. 340069. Store at 4°C. ([more info](#))

Physical description: Screw top tubes in freezer box containing lyophilized powder.

Microbiologics

Catalogue no. HE0065N. Store at 4°C

Helix Elite Inactivated SARS-CoV-2 Whole Virus (Pellet); ([more info](#))

Physical description: Clear plastic bag containing 4 mylar bags.

ThermoFisher

AcroMetrix SARS-CoV-2 Control; Catalogue no. 954517. Store at -20°C. ([more info](#))

Physical description: Screw top tubes in freezer box.

LGC SeraCare

AccuPlex™ SARS-CoV-2; Catalogue no. 0505-0168. Store at 4°C. ([more info](#))

Physical description: Screw top tubes in freezer box.

NIBSC

SARS-CoV-2 RNA; Catalogue no. 20/138. Store at -20°C. ([more info](#))

Physical description: Glass vials bubble wrapped in clear bag in second freezer box.

Asuragen

Armored RNA Quant SARS-CoV-2 Control; Catalogue no. 52036. Store at -20°C. ([more info](#))

Physical description: Screw top tubes in freezer box. Next to TSM III dilution buffer.

Imperial College

MS2-SARS-CoV-2 nucleocapsid gene Virus-like Particles; non-commercial. Store at -20°C. ([more info](#))

Physical description: 2 mL snap cap tube containing frozen liquid. located either in freezer box or in 50 mL conical tube inside of a clear plastic bag. This sample should be considered optional at the labs discretion due to packaging failure.

WHO International Standard (NIBSC)

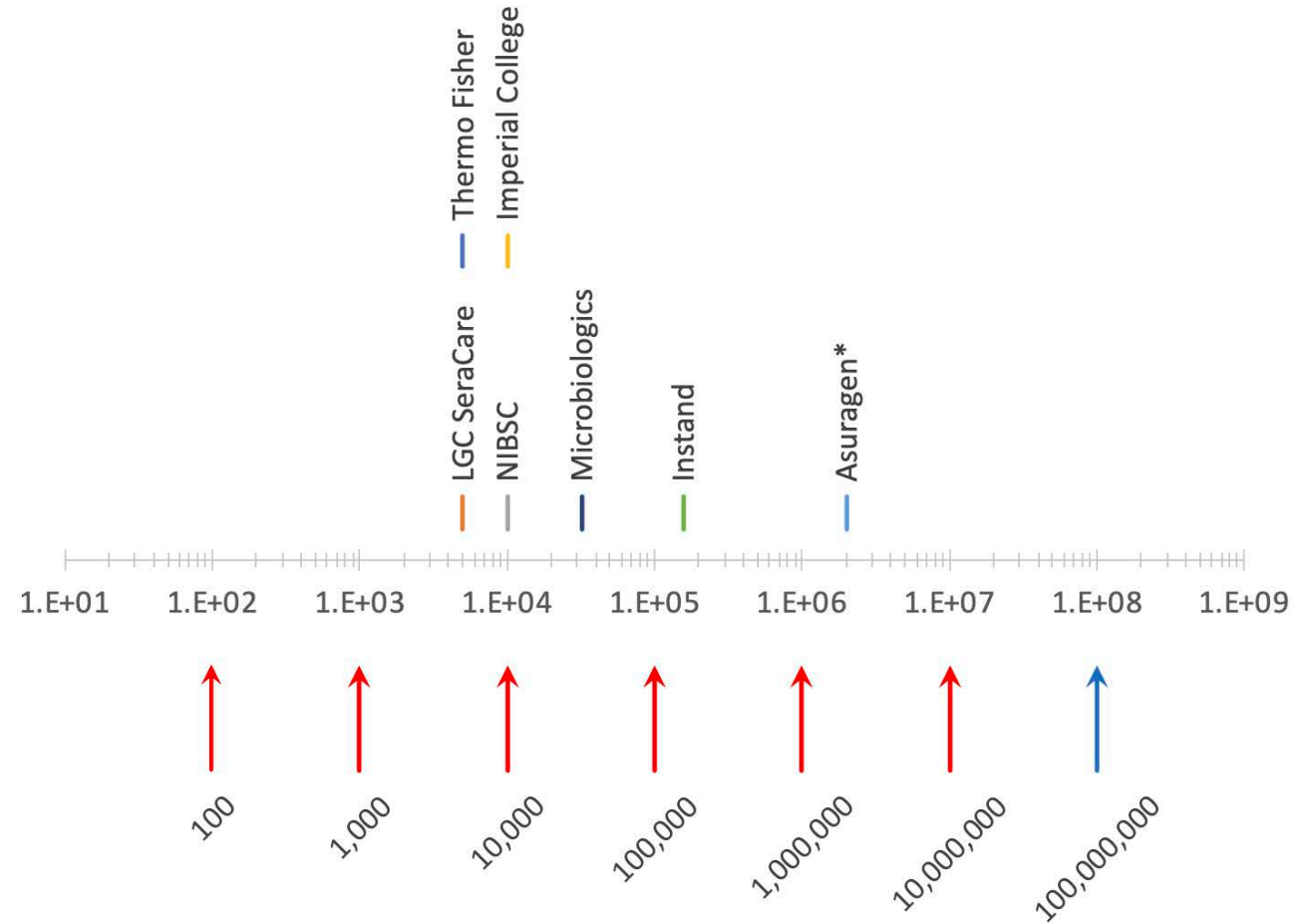
NIBSC code: 20/146. Store at -20°C. ([more info](#))

Physical description: Glass vials bubble wrapped in clear bag in second freezer box.

Note -- The original study design included a sample from Zeptomatrix, which is NOT included in the study.

SOP Updated to reflect changes

- Updated Google Doc
 - Concentration number line
 - Design
 - Tables
 - Refinements



Coordination of tests

- "Which test do you want us to use?"
 - whichever you have best confidence in!
 - you can note your top 2 choices and we'll try to best cover the landscape

The screenshot shows a Google Sheet with the following data:

	A	B	C	D
1	Lab	Contact email	First-choice test	Second-choice test
2	Bio-Rad Laboratories	monica_herrera@bio-rad.com	Bio-Rad SARS-CoV-2 ddPCR Kit (EUA)	N/A
3	Biodesix	gary.pestano@biodesix.com	Bio-Rad SARS-CoV-2 ddPCR Kit (EUA)	N/A
4	Stanford	bpinsky@stanford.edu; kobadiamfuh@stanfordhealthcare.org	Perkin Elmer (EUA)	Stanford E gene (EUA)
5	MUSC	nolte@musc.edu	Abbott Alinity m (EUA)	Abbott m2000 EUA
6				
7				
8				
9				
10				
11				

The sheet interface includes a menu bar with 'File', 'Edit', 'View', 'Insert', 'Format', 'Data', 'Tools', 'Add-ons', and 'Help'. The status bar at the bottom shows '+', a hamburger menu icon, and 'Preferred Tests'.

Timeline for results

April 9

Mark Page, NIBSC

Creating the WHO antibody reference
panel



**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. Bentley¹, Mark Hassall¹, Stephanie Routley¹, Samuel Richardson¹, Valentina Bernasconi², Paul Kristiansen², Heli Harvala³, David Roberts³, Malcom G Semple⁴, Lance CW Turtle⁴, Peter JM Openshaw⁵ and Kenneth Baillie⁶ on behalf of the ISARIC4C Investigators, Lise Sofie Haug Nissen-Meyer⁷, Arne Broch Brantsæter⁸, Helen Baxendale⁹, Eleanor Atkinson¹⁰, Peter Rigsby¹⁰, David Padley¹¹, Neil Almond¹¹, Nicola J. Rose¹, Mark Page¹ and the collaborative study participants*



Discussion

