

4 December 2020

Marc Salit,
JIMB Director

SLAC National Lab
Stanford University

Harmonization Study Participation Status, Logistics, Analysis Plans

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.

Harmonization Study Materials, Participants, Timeline, Next Steps for Reporting, & Analysis



Materials in
Study



Labs in Study



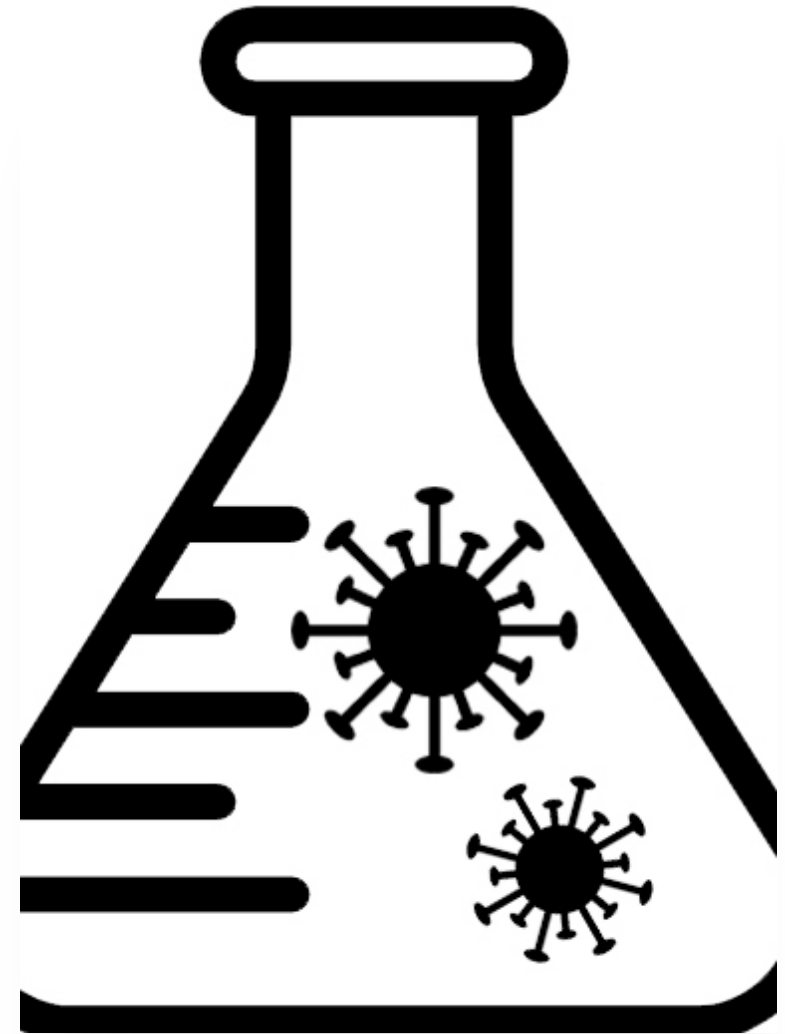
Timeline



Reporting
Platform



Analysis
Platform



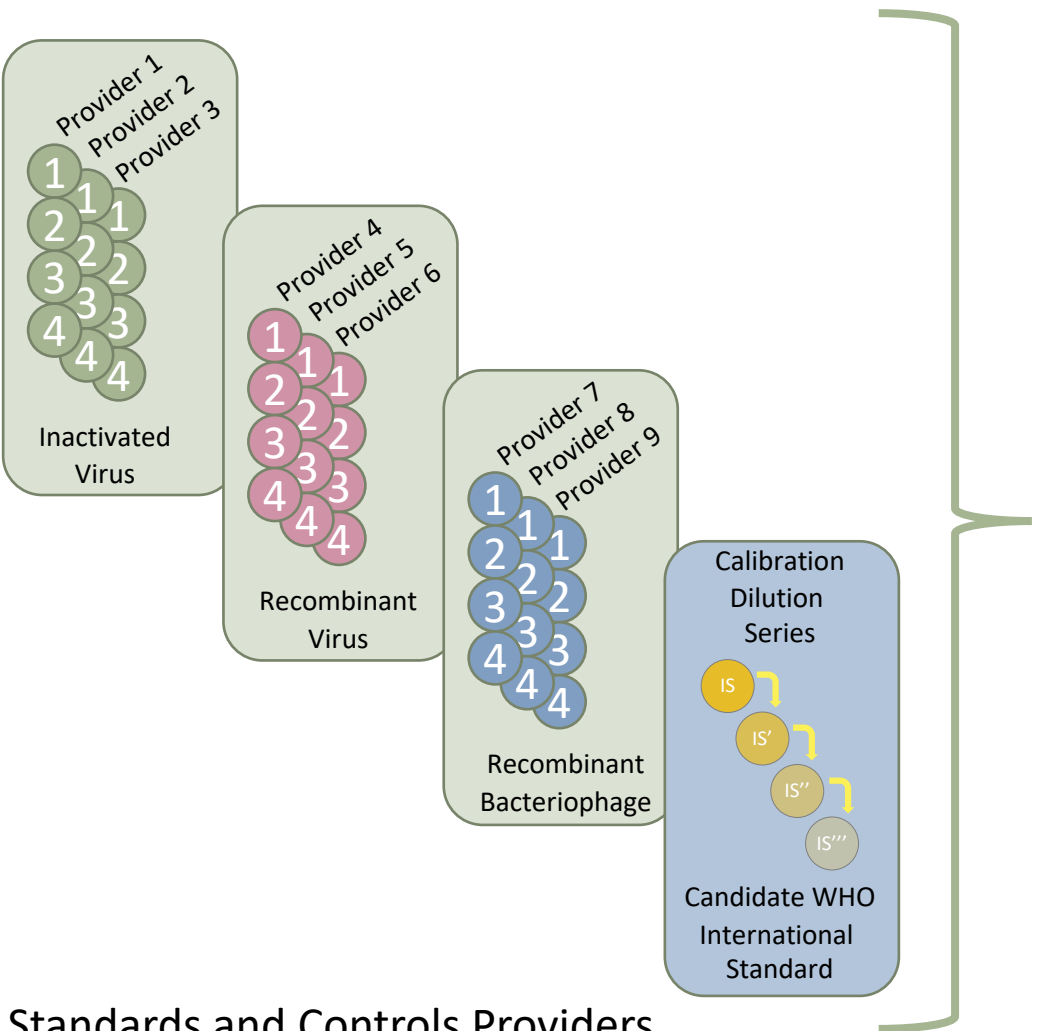
Purpose of Harmonization Study

The CSWG “Harmonization Study” will establish the equivalence of SARS-CoV-2 RNA target concentrations across a panel of materials and calibrate those results against the WHO International Standard (IS) reference sample.

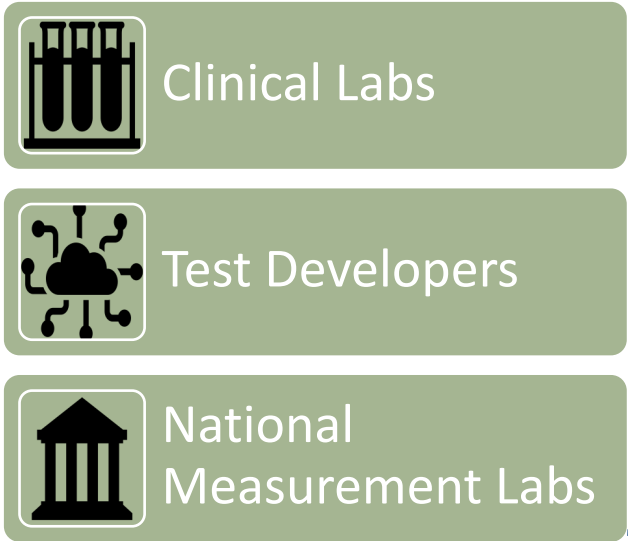
By calibrating with the WHO International Standard (IS) the values on the materials included in this study can be assigned in the International Unit for SARS-CoV-2.



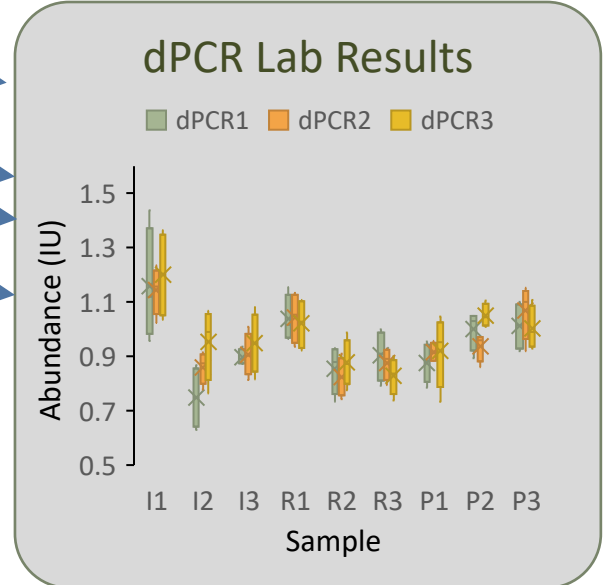
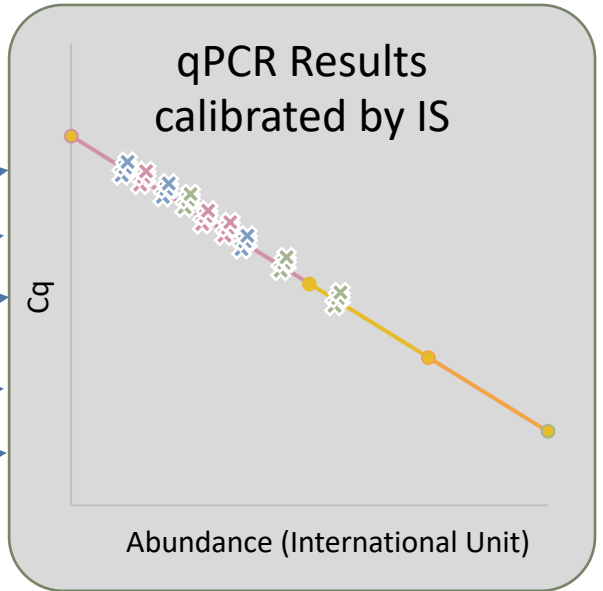
CSWG Harmonization Study Design



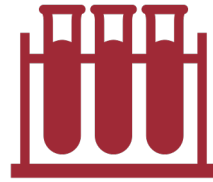
Standards and Controls Providers will contribute materials to be compared to candidate WHO International Standard (IS) with RT-qPCR and dPCR.



Labs will measure study materials calibrated with candidate IS. All results will be harmonized to the value of the IS.



What this study is not going to do



a comparison of tests



a comparison of labs



a survey of method performance (LOD, precision, repeatability)



an evaluation of commutability

What are the samples in our study panel?

Provider	Material Description	Class of Material	Full Genome?	Provider Confirmation	Material Received	Comments
Instand	Lyophilized cell lysate	Inactivated Virus	TRUE	TRUE	30 Nov 2020	in JIMB Freezer
Zeptomatrix	x 0.5 mL of NATtrol™ SARS-CoV-2	Inactivated Virus	TRUE			
Thermo Fisher	Lyophilized cell lysate	Inactivated Virus	TRUE	TRUE	17 Nov 2020	in JIMB Freezer
Microbiologics	Lyophilized cell pellet	Inactivated Virus	TRUE	TRUE	19 Nov 2020	in JIMB Freezer
NIBSC	Lyophilized Viral Isolate	Inactivated Virus	TRUE	TRUE		Proposed WHO international standard
Assuragen	Pseudo-Viral Particles	Packaged encapsulated RNA	FALSE	TRUE	11 Nov 2020	in JIMB Freezer
Imperial College	Packaged encapsulated RNA	Packaged encapsulated RNA	FALSE	TRUE		
LGC SeraCare	Non-SARS viral particles in solution	Recombinant Virus	TRUE	TRUE	17 Nov 2020	in JIMB Freezer
NIBSC	Non-SARS viral particles in solution	Recombinant Virus	TRUE	TRUE		

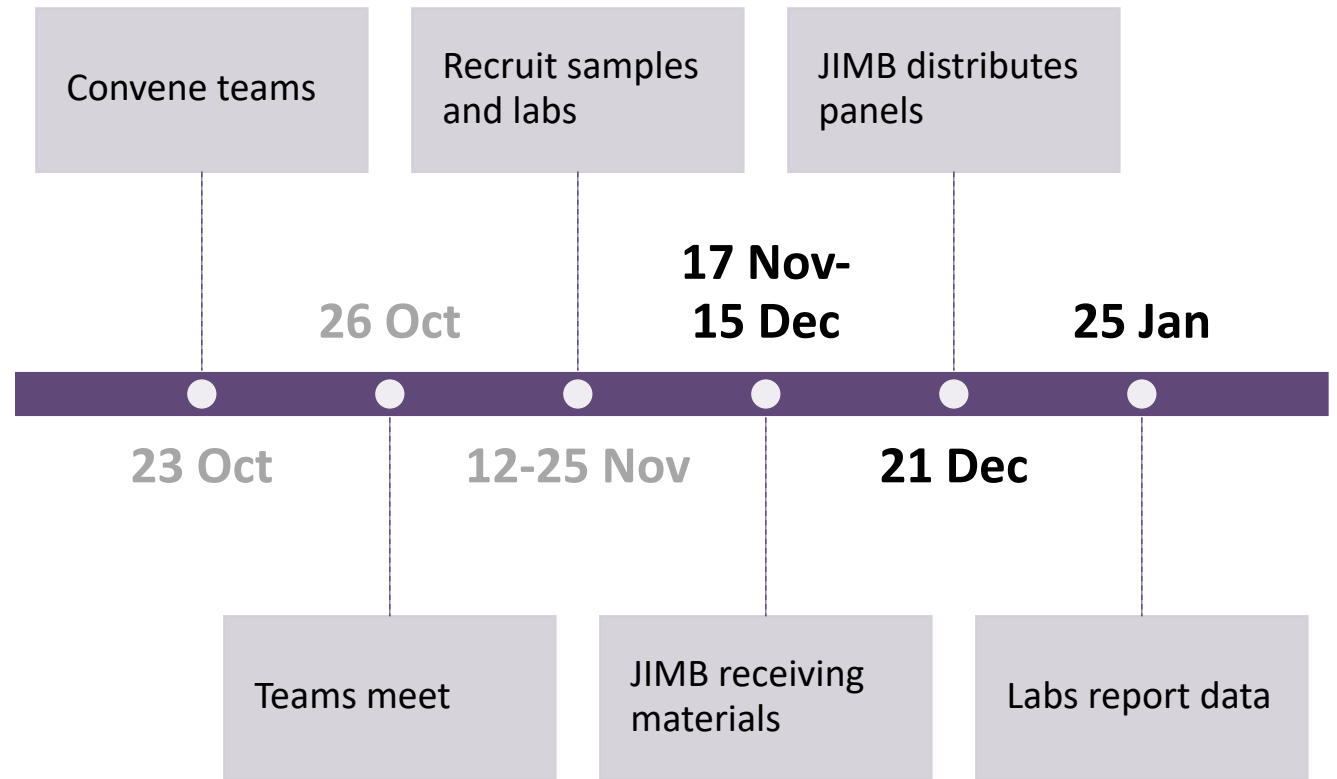
Who are the labs in our study?

Labs to meet Tuesday 8 December at 1030 PST/1330 EST/1830 GMT/1930 CET

- Which tests to run at which labs?
- What are the critical protocol elements?
- What performance metrics to report?

Lab	Type	Location	Technology	Lab Confirmation
Western	Clinical Lab	Los Angeles, CA	qPCR	TRUE
MUSC	Clinical Lab	Charleston, SC	qPCR	TRUE
Mayo	Clinical Lab	Rochester, MN	qPCR	TRUE
Labcorp	Clinical Lab	Burlington, North Carolina	qPCR	TRUE
Quest	Clinical Lab	Seacaucus, NJ	qPCR	TRUE
Biogazete	Clinical Lab	Belgium	qPCR	TRUE
MassCPR Diagnostics	Clinical Lab	Boston, MA	qPCR	TRUE
Stanford Medicine	Clinical Lab	Stanford, CA	qPCR	TRUE
Los Alamos	Clinical Lab	Los Alamos, NM	qPCR	TRUE
biodesix	Clinical Lab	Boulder, CO	dPCR	TRUE
NIST	National Measurement Institute	Gaithersburg, MD, USA	dPCR	TRUE
NML	National Measurement Institute	Teddington, UK	dPCR	TRUE
NIB	National Measurement Institute	Ljubljana, Slovenia	dPCR	TRUE
Bio Rad	Test Developer	Pleasanton, California	dPCR	TRUE

Timeline & Logistics



Reporting



Platform

JIMB to work with Curii



Protocol Information

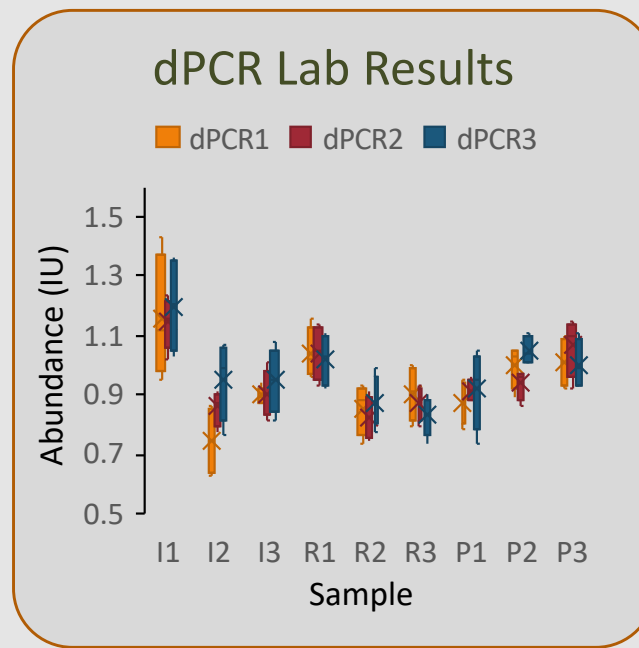
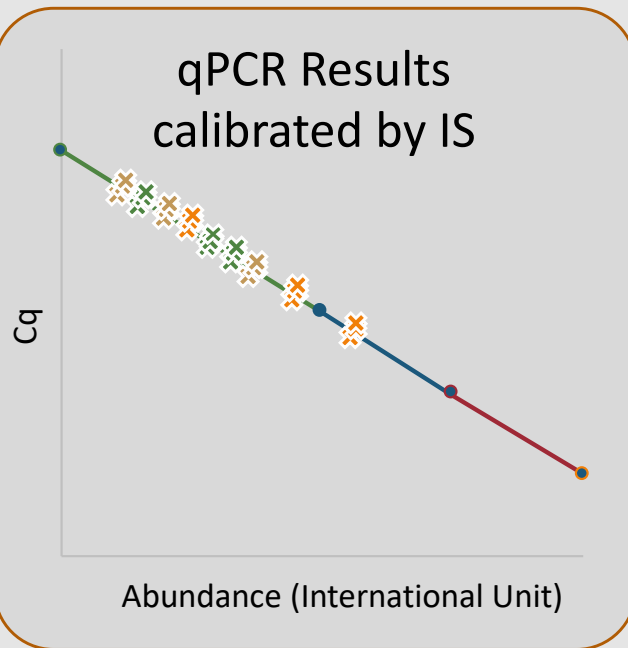
MIQE Table



Spreadsheet Report Form

see NIBSC tool

Analysis



- Focus on value assignment of 8 materials against the WHO IS
- Analysis and data evaluation inspired by experience with CCQM Comparisons
- Distribution analysis to harmonize results
 - establish measurement uncertainty from population of results



Discussion