23 October 2020

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Harmonization Study Planning

Coronavirus Standards Working Group

What should a Coronavirus Standards Working Group do?

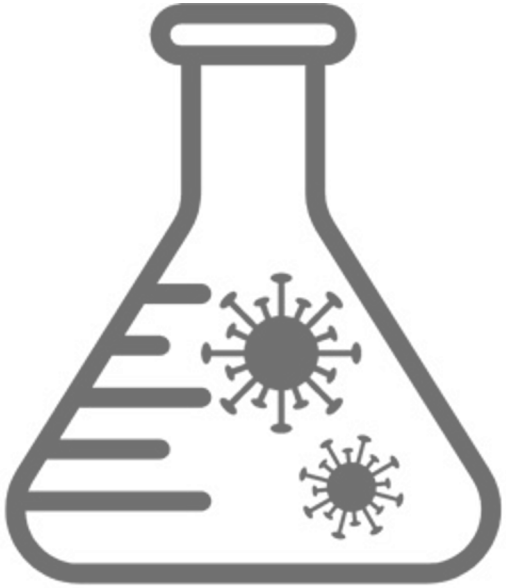
Assure development and availability of standards, controls, interlab testing, knowledge to support successful rollout & scaling of 2019-nCoV testing

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 to Finalize Harmonization Study

Statement of Purpose

What this study will not cover

Design principles

Questions to resolve

sample type(s)

experiment design

labs

Analysis plan

Timeline

Team leads

* Samples
* Labs
* Design & Analysis

Purpose of Harmonization Study

The CSWG “Harmonization Study” will compare a panel of SARS-CoV-2 controls and calibration materials to put them on the same abundance scale.

By including the NIBSC sample intended to establish the International Unit (IU), the values on the materials included in this study can be made traceable to the IU when it becomes available.

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

Design Principles

use full process controls that can be inserted in the process at extraction

- higher bar: can be added to a negative clinical sample

use “Catalog” products just as they would be provided to a user

- where available in catalog products, multiple dilutions welcome

material identities to be open, “unblinded”

- accompanied with full descriptions

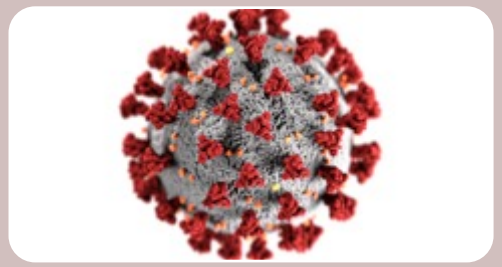
JIMB lab will…

- draft a protocol & manage logistics

labs will report

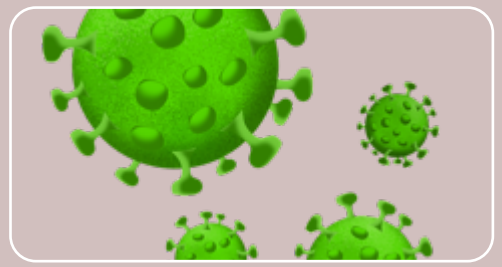
- Cq or digital PCR results

Sample design decisions



inactivated virus

- mimics clinical sample

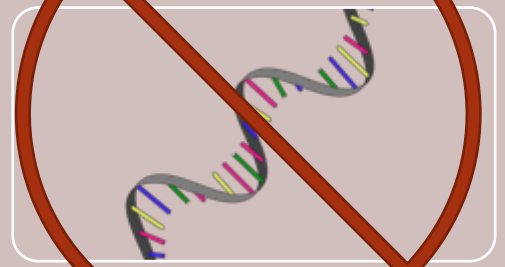


recombinant virus

- good reproducible mimic

“packaged” RNA

- reproducible, accessible, effective control



“naked” RNA

- very accessible and readily characterized

Which labs?
How many?

- National Measurement Labs
- Test Developers
- Clinical Labs
  - Academic
  - Commercial

Experiment Design and Analysis

Dilution/calibration scheme

protocol considerations

Replication

Comparability assessment

across labs

across materials

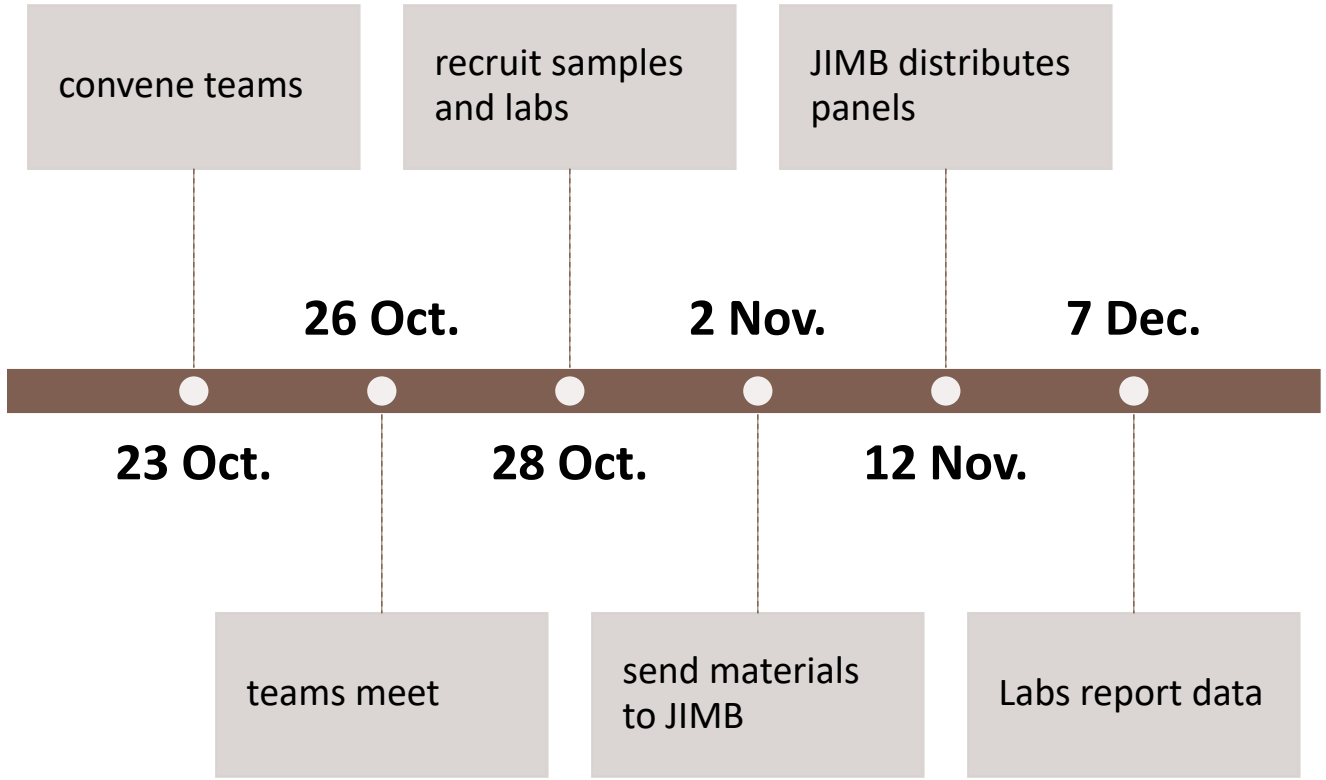
relative value assignment

absolute value assignment

Teams: Samples, Labs, Reporting, Analysis Plan

Samples Team	• develop sample panel
Labs Team	• assemble & coordinate labs
Reporting Team	• draft reporting template • MIQE, digital MIQE
Experiment Design & Analysis Team	• design experiment • compose analysis plan

Timeline


convene teams
recruit samples and labs
JIMB distributes panels
26 Oct.
2 Nov.
7 Dec.
23 Oct.
28 Oct.
12 Nov.
teams meet
send materials to JIMB
Labs report data