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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…

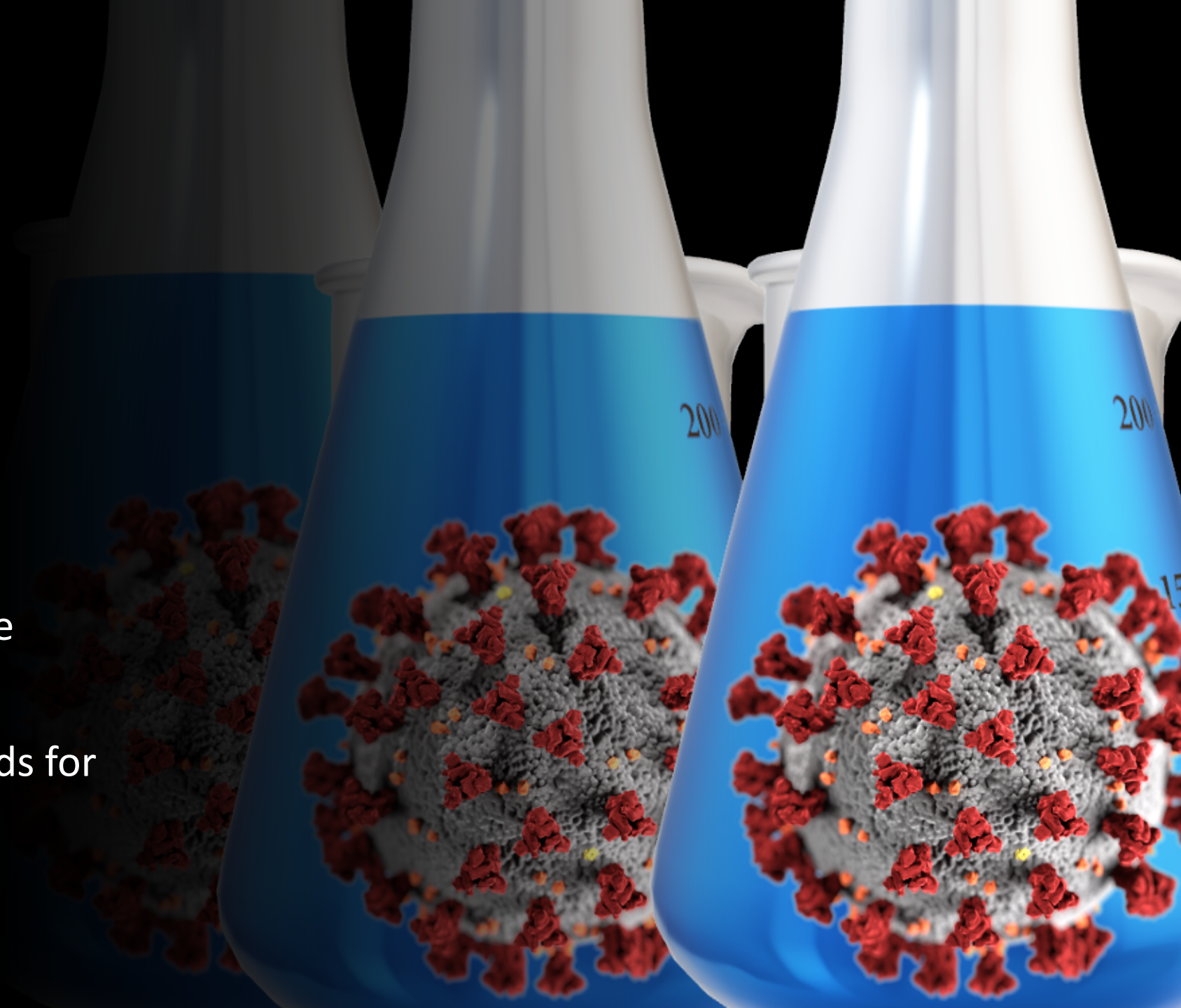
- confidence in test results
- interoperability
- scale-up
- long-term capacity

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.

Agenda

- WG Roadmap
- Progress on an annotation standard for an inventory of COVID-19 controls/reference samples/standards
- Measurements and Standards for Serology



Working Group Roadmap

We're in Week 3 of developing this WG.

Key that we pose a set of objectives and paths to work toward them.

Use objectives as strategy to decide and prioritize.

Use objectives and the cadence of near, mid, and enduring terms to articulate our story and identify key stakeholders and participants.

We need to keep the roadmap up to date in the evolving COVID-19 pandemic.

Near-term

- Annotated inventory of standards and controls
- Watch inventories of assays, engage to assure assays are sufficiently described
- Consider interlab study to evaluate population of controls

Mid-term

- Explore clinical repository
- Explore needs for serological standards
- Explore needs for information clearinghouse(s)

Enduring

- Institutionalize the Working Group as a network
- Evolve with what we learn this time

Standards Inventory

- Jim Huggett, LGC
- Pete Vallone, NIST
- Robyn Temple-Smolkin, AMP

Team reaching out to vendors to create annotated inventory of available materials

Basis of a Minimum Information About A COVID Standard Standard

Attribute
Safety level
Vendor or Origin
Item Name
Catalog #
Type of material
Regions of the genome
Volume
Concentration
Stabilizer
Storage
Cost
Web links
Order placed
Order received
Other comments
*** Sampling steps**
specimen taking
storage-transport
*** Extraction steps**
lysis
purification
*** Assay steps**
reverse transcription
PCR

Considering Serological Testing and Standards

Preston Estep

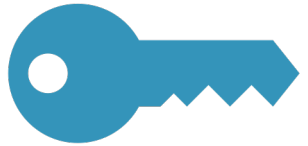
Critical innovation for testing

informing on exposure/immunity status

informing on prevalence of disease and immunity

identifying donors for convalescent antibody therapies

informing therapeutic development



Antigen reactivity with human antibodies being published

methods for systematic characterization of reactivity

development and deployment of controls and standards

All other business

How are we doing? Communications, planning, engagement, process, operations?

Discussion