

3 April 2020

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SLAC National
Lab and Stanford
University

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.

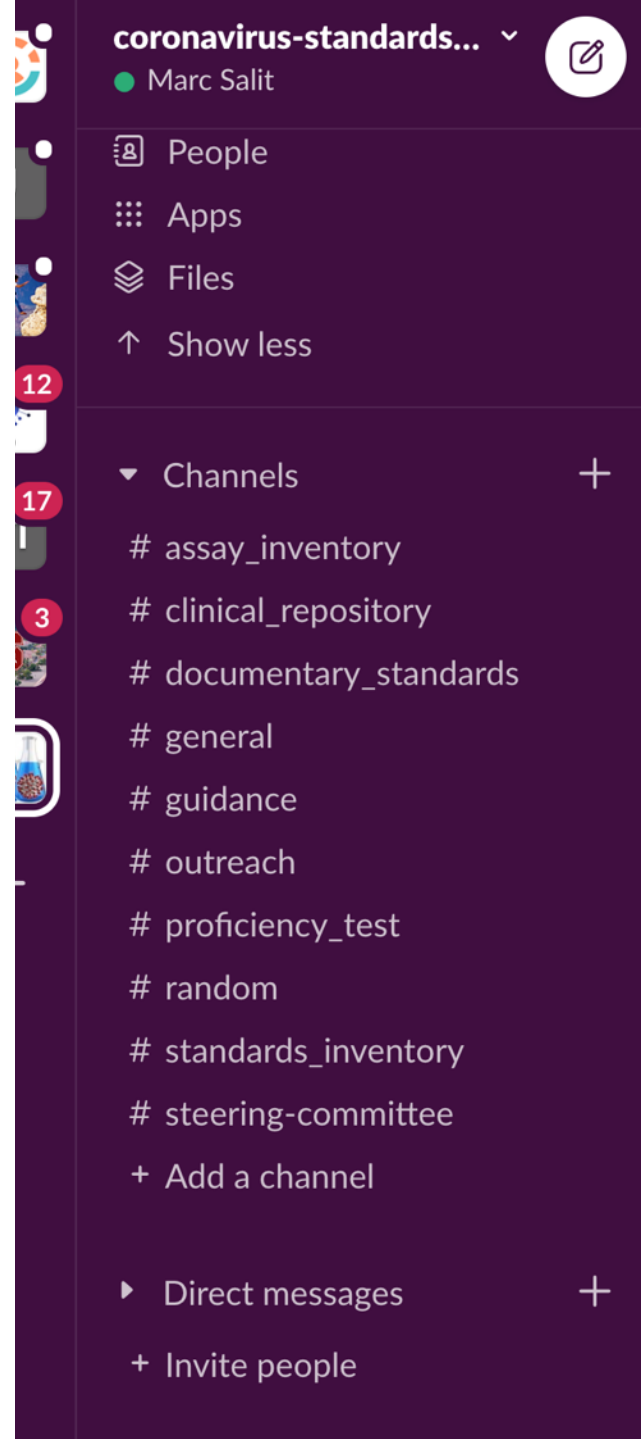
The background of the slide features three white Erlenmeyer flasks arranged in a row, slightly overlapping. Each flask is filled with a blue liquid. Inside the flasks, there are 3D models of the COVID-19 virus, depicted as grey spheres with red, crown-like spikes. The flasks are labeled with '200' and '15' on their sides. A small teal horizontal bar is located in the top left corner of the slide.

Agenda

- WG resources – Slack workspace
- Work on an annotation standard for an inventory of COVID-19 controls/reference samples/standards
- Available documentary standards, Gaps?
- Considerations for a clinical repository
- WG scope – do we need an Assay inventory?

Slack Workspace

- All welcome, open, unmoderated
- Asynchronous and archival
- Threaded
- Subgroups have channels



The screenshot shows the Slack sidebar for a workspace named "coronavirus-standards...". At the top, there is a search bar with "Marc Salit" entered. Below the search bar are navigation options: "People", "Apps", "Files", and "Show less". The "Channels" section is expanded, showing a list of channels: "# assay_inventory", "# clinical_repository", "# documentary_standards", "# general", "# guidance", "# outreach", "# proficiency_test", "# random", "# standards_inventory", "# steering-committee", and "+ Add a channel". Below the channels are "Direct messages" and "+ Invite people".

Threads

2 new replies



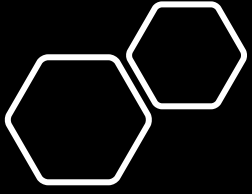
Marc Salit 2 days ago

Hi all — below is a mashup of tables from [@Pete Vall](#)
Minimum Information About a Coronavirus 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
```



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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

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purification

*** Assay steps**

reverse transcription

PCR



Kathy Castagna from CLSI



Search standards and more...



Standards

Support

More



CLSI Documents Helpful for COVID-19 Testing

This list of documents have been identified as helpful for the laboratory community's use during the current pandemic.

Click the document areas below to view related documents, more information about their help with COVID-19 testing, and access their sample pages.

[Download a PDF Version of this List](#)

[Additional COVID-19 Resources](#)

ISO TC276 makes biotechnology standards

Sheng Lin-Gibson, NIST

Standardization in the field of biotechnology processes that includes the following topics:

- Terms and definitions;
- biobanks and bioresources;
- analytical methods;
- bioprocessing;
- data processing including annotation, analysis, validation, comparability and integration;
- metrology.

ISO/TC 276 Biotechnology will work closely with related committees in order to identify standardization needs and gaps, and collaborate with other organisations to avoid duplications and overlapping standardization activities.

ISO

ICS > 07 > 07.080

ISO 20395:2019

Biotechnology – Requirements for evaluating the performance of quantification methods for nucleic acid target sequences – qPCR and dPCR

This standard is available for free in read-only format

ABSTRACT [PREVIEW](#)

This document provides generic requirements for evaluating the performance and ensuring the quality of methods used for the quantification of specific nucleic acid sequences...

Clinical Repository – can we work with the PGP?

Sarah Wait Zaranek



International Projects

The Global Network of Personal Genome Projects includes researchers at leading institutions around the globe:

- **Harvard PGP (United States)**

Founded in August 2005, the Harvard Personal Genome Project is the pilot PGP site, and is based in George Church's laboratory at Harvard Medical School.

[Go to the Harvard PGP website](#)

- **PGP Canada (Canada)**

Founded in December 2012, PGP Canada is operated by the McLaughlin Centre at the University of Toronto, and The Centre for Applied Genomics at the Hospital for Sick Children.

[Go to PGP Canada website](#)

- **PGP UK (United Kingdom)**

Founded in November 2013, PGP UK is led by Stephen Beck at University College London.

[Go to the PGP UK website](#)

- **Genom Austria (Austria)**

Founded in November 2014, Genom Austria is based at the CeMM Research Center for Molecular Medicine of the Austrian Academy of Sciences.

[Go to Genom Austria website \(German language\)](#)

- **PGP China (People's Republic of China)**

Announced in October 2017, The Personal Genome Project in China (PGP China) is led by Professor Li Jin at Fudan University, Shanghai. PGP China is now collecting contact information from interested participants and potential collaborators.

[Go to the PGP China website \(in Chinese and English\)](#)

- The Personal Genome Project is “dedicated to creating public genome, health, and trait data. Sharing data is critical to scientific progress...”
 - The PGP approach is to invite willing participants to publicly share their personal data for the greater good.”
- Participants rigorously consented
 - samples can be used without restriction
- A repository of openly-consented samples would be a precious resource for public health response, diagnostics, and science
 - collect pre-infection, infected, recovered

<https://www.personalgenomes.org>

Coronavirus Test Tracker: Commercially Available COVID-19 Diagnostic Tests

As labs and diagnostic developers race to meet demand for assays to detect the SARS-CoV-2 coronavirus, 360Dx is updating this tracker on a regular basis in order to provide readers with up-to-date and accurate information on the regulatory status of these tests in the US, European, and Asian markets.

The tracker includes only those tests that are available for diagnostic use. Links to primary regulatory decisions are provided where available.

Last updated: April 2, 2020.

Company/Organization Name	Test Name	US Regulatory Status	EU Regulatory Status	Asia Regulatory Status	Technology
3D Medicines	SARS-CoV-2 and Influenza A & B RT-qPCR Detection Kit		CE mark 3/2020		PCR
Abbott	ID Now COVID-19	EUA 3/27/2020			isothermal amplification
Abbott	Abbott RealTime SARS-CoV-2 EUA test	EUA 3/18/2020			PCR
Anatolia Geneworks	Bosphore Novel Coronavirus (2019-nCoV) Detection Kit		CE mark 2/2020		PCR
ARUP Laboratories	COVID-19	EUA planned			PCR
A*STAR, Tan Tock Seng Hospital of Singapore	A*STAR Fortitude 2.0			Singapore Health Sciences Authority, provisional authorization for clinical use	PCR
Assure Tech	COVID-19 IgG/IgM Rapid Test Device	notified FDA under			Serological

Test Kit Manufacturers and Commercial Laboratories Table:

Search: Show entries

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Fact Sheet for Healthcare Providers	Fact Sheet for Patients
04/02/2020	Becton, Dickinson & Company (BD)	BioGX SARS-CoV-2 Reagents for BD MAX System	Healthcare Providers	Patients
04/01/2020	Ipsium Diagnostics, LLC	COV-19 IDx assay	Healthcare Providers	Patients
04/01/2020	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test	Healthcare Providers	Patients
03/30/2020	QIAGEN GmbH	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Healthcare Providers	Patients
03/30/2020	NeuMoDx Molecular, Inc.	NeuMoDx SARS-CoV-2 Assay	Healthcare Providers	Patients
03/27/2020	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay	Healthcare Providers	Patients
03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19	Healthcare Providers	Patients

Other Orgs are working on Assay Inventories

360Dx and FDA are both sources for deep information about assays.

We might focus on how the standards in our inventory work with the different assays.

Discussion