Coronavirus Standards Working Group

Steering Committee Meeting Summary
3 April 2020

Thanks again to all who attended the Steering Committee meeting today (or tomorrow, for some!) for your focused engagement. Paraphrasing a remark made by a friend and colleague who is working with this group -- “it’s good to be doing something to help.”

We again had representation from professional societies, clinical and academic labs, government agencies, commercial assay makers, commercial standards producers, NGOs and international organizations.

The slides presented at the meeting and this report will be posted on the JIMB webpage and in our Slack workspace.

Our next meeting will be Friday 10 April 2020 at 0800PDT on Zoom at this link: https://stanford.zoom.us/j/377060585. All are welcome.

Key follow-ups

- Continue to develop and update our #standards_inventory (All, Jim and Pete)
    - We are compiling available QC resources and reaching out to vendors for use-cases and product details.
    - Please add what you know about other available QC standards.
    - We will add knowledge about product availability, regional availability, ease of access, application design notes
- Start developing roadmap for serological testing and standards (Preston, Marc, others)
- Maintain and refine documentary standards inventory developing on Slack channel -- please add what’s missing (all, Kathy)
- Develop considerations that need to be addressed to create repository based on PGP COVID-19 Project (Marc, Sarah, PGP, others)

Follow-ups will use the Slack, and all are welcome to observe and participate.

Discussion topics

Marc reviewed the Working Group charge, and presented the SC meeting agenda, which covered the Slack workspace, the Standards Inventory (Pete and Jim), Documentary Standards

(Kathy and Sheng), the PGP COVID project (Sarah), and a brief consideration of whether an Assay Inventory was in scope.

WG resources – Slack workspace (anyone is welcome to help with a logo design) – this resource is intended to be the main communications platform for our WG. It is asynchronous, threaded, archival, and amenable to organization of topics by channel.

Standards Inventory – Pete and Jim presented their work developing an inventory of COVID-19 controls/reference samples/standards with a focus on assuring information on a common set of attributes, including what parts of a test/assay are controlled for by a particular material. Work on this inventory is ongoing. It's possible that the common attribute annotation can be established as a "Minimum Information Standard." Pete and Jim are reaching out to manufacturers to compile complete annotation. Annotation will be added on availability of materials and any regional restrictions.

There was discussion of whether the scope of this inventory extends beyond nucleic acid testing to serological testing. Serological testing for COVID-19 is far less mature at present, and will be a future consideration of the WG. Marc will work with Preston Estep to scope (see Resources below for links to early work on serological antibody test research and protocols).

It was noted that there is an inactivated viral control material available from ATCC, and Mayra Garcia noted that there is a live virus strain control available from BEI, which is a BSL-3 material. Neil Almond described the NIBSC material in development that contains COVID-19 genetic material in an alternative active virus, certified safe to work with outside of BSL-3.

Discussion of quantitative molecular assays identified numerous challenging factors, most notably pre-analytical biases (in particular sampling swab and extraction effects). This topic may rise in the future. Noteworthy is that at present viral load is a research question, not a clinical question (thanks Tim Minogue, Jo Vandesompele, Kate Griffiths, Marya, Jim, Robyn T-S).

Documentary Standards – Kathy Castagna presented the CLSI COVID-19 related standards listing released this week. This catalog offers guidance on the breadth of laboratory practice: specimen collection, verification, evaluation protocols, safety, point of care testing, quality management systems, statistical analysis. Some documents are free for limited time use. CLSI will consider needs for more on a case-by-case basis. The link to the catalog is posted in the Slack #documentary_standards channel. CLSI are interested in input on gaps, particularly from lessons learned and future preparedness.

Sheng Lin-Gibson presented the work of ISO TC 276, and in particular the relevant 2019 standard on performance of quantitative and digital PCR (see links in Resources below and on the Slack #documentary_standards channel. This document has been made freely available by ISO. ISO and other SDOs are working together to make other relevant standards freely available - for instance, covering PPE and ventilators. Clinical serological testing standards may be in scope.

Considerations for a Clinical Repository – We began our considerations for a Clinical Repository with a presentation of the PGP COVID-19 project, by Sara Wait Zaranek. Sarah's slides are available on the Slack #clinical_repository channel. Key attributes of the PGP project underway are the rigorous consent that permits ethical unrestricted use of samples gathered from individuals who share genomic, environmental, and human trait data openly donated. Initial engagement by PGP for the COVID-19 resulted in 636 participants, ongoing engagement is 364.

A repository of such openly-consented samples — we can collect pre-infection, infected, post-infection — would be a precious resource for public health response, diagnostics, and science.

We will pursue the questions surrounding establishing a clinical repository and revisit it at a future SC meeting, working on the Slack #clinical_repository channel (Marc, Sarah, Neil, others).

Assay Inventory — The final topic was to briefly consider whether an #assay_inventory is in scope. The FDA EUA website contains a deep inventory of assays approved under the EUA, and the 360Dx Coronavirus Test Tracker is another resource. We will revisit the topic, especially as we can consider the appropriateness of the different standards for the different assays.

Resources

- Assay Inventories
    - https://www.finddx.org/covid-19/
- Genomic Information
    - https://www.gisaid.org
    - https://nextstrain.org/ncov
- Documentary Standards
    - https://clsi.org/standards-development/helpful-documents-for-covid-19-testing/
    - https://www.iso.org/standard/67893.html
- Serological Testing Research
    - https://labs.icahn.mssm.edu/krammerlab/covid-19/
    - https://www.medrxiv.org/content/10.1101/2020.03.17.20037713v1