3 April 2020
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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 do next time we have a global network in place ready to make standards.
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
Team reaching out to vendors to create annotated inventory of available materials

Basis of a Minimum Information About A COVID 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
Kathy Castagna from CLSI

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.
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.


<table>
<thead>
<tr>
<th>Company/Organization Name</th>
<th>Test Name</th>
<th>US Regulatory Status</th>
<th>EU Regulatory Status</th>
<th>Asia Regulatory Status</th>
<th>Technology</th>
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<tr>
<td>3D Medicines</td>
<td>SARS-CoV-2 and Influenza A &amp; B RT-PCR Detection Kit</td>
<td>CE mark 2/2020</td>
<td>ISO 13485:2012</td>
<td>PCR</td>
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<td>ARUP Laboratories</td>
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<td>A*STAR Test Task Group, Hospital of Singapore</td>
<td>A*STAR Fortitude 2.0</td>
<td>Singapore Health Sciences Authority, provisional authorization for clinical use</td>
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<td>Assure Tech</td>
<td>COVID-19 IgG/IgM Rapid Test Device</td>
<td>notified FDA under</td>
<td>ISO 13485:2012</td>
<td>Serological</td>
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</tbody>
</table>

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