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PROPOSED 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



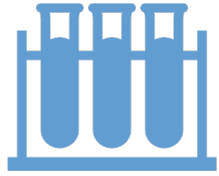
Identify and develop critical infrastructure to support...

- 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.



Resources for Test Development

Analytical and clinical reference materials, standards, and controls

Materials for inter-laboratory studies and proficiency testing

Build a repository of clinical samples of 2019-nCoV for technology development and validation



Resources for Test Validation

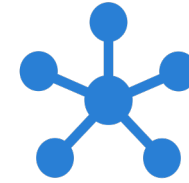
Interlab and Proficiency Testing Studies

- assess lab-lab and assay-assay performance and variability

Sharing of best practices and validation protocols

Open repository of validation results and comparative studies

Enduring documentary standards



Build a Network

“clearinghouse” for supply chain availability

- kit availability, control material availability, kit performance, lab capacity
- tools to load-balance surge capacity

WHAT SHOULD WE MAKE?

PROPOSED WORK



Inventory and gap analysis of controls, standards, assays



Open repository of validation data, methods, and protocols



Setting priorities



Interlab study to evaluate comparability of standards, controls, and assays



Standards Development



Repository of Clinical Samples

WHAT AN ANNOTATED INVENTORY MIGHT LOOK LIKE...

	<i>Sampling</i>		<i>Extraction</i>		<i>Assay</i>	
	Specimen Taking	Storage & Transport	Lysis	Purification	RT	PCR
<i>Asuragen</i>			√	√	√	√
<i>ATCC</i>			√	√	√	√
<i>BEI Resources</i>			√	√	√	√
<i>Bio-Rad</i>					√	√
<i>IDT</i>						√
<i>INSTAND</i>			√	√	√	√
<i>JRC</i>					√	√
<i>Microbiologics</i>					√	√
<i>NIM China</i>			√	√	√	√
<i>SeraCare</i>			√	√	√	√
<i>Sigma Aldrich</i>						
<i>Thermo Fisher</i>						
<i>Twist Bioscience</i>					√	√
<i>UTMB - Galveston</i>						
<i>ZeptoMetrix</i>			√	√	√	√

- NB: empty cells denotes unknown; multiple products may be available providing control of different steps

- Table thanks to Jim Huggett of LGC

- Tip-of-the-Hat to Robyn Temple-Smolkin of AMP for the inventory

KEY PARTNERS AND STAKEHOLDERS



Professional Societies



Clinical & Academic Labs



Government



Commercial Assay makers



Commercial Control
makers



NGOs and International Orgs

AGENDA



Review the purpose of the Working Group



Consider the proposed portfolio and identify missing parts



Prioritize the work



Establish roles for the partners



Establish ways of working

DISCUSSION