Coronavirus Standards WG Steering Committee

Dear Colleagues -

Thanks for your active engagement at today's CSWG meeting. The takeaway from our meeting is to design the harmonization study with emphasis on "whole process" controls, and move forward establishing the details.

This note includes survey questions to help get those details in place. There are separate sets of questions for organizations that can provide materials and organizations that can provide measurements, or "test results."

PLEASE RESPOND TO THESE SURVEY QUESTIONS BY TUESDAY 6 OCTOBER (by email to me, <u>msalit@stanford.edu</u> - I will also start a Slack thread on this topic in the #interlaboratory channel). Please also feel free to make any suggestions or remarks that aren't covered in the survey! Let's get this to be good enough to go!

The *Real and Urgent Value Proposition* for this study is to: Have a number of "good" labs each measure the relative levels of viral genomic material in a panel of Type 2 "Whole Process" Controls/Standards.

The slides used this morning are linked <u>here</u>, and the meeting recording is linked <u>here</u>.

The Survey Questions follow below.

Marc

Harmonization Study Survey

Participating Labs

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- What types of samples can you measure in your lab? (viral mimics in VTM, viral mimics in buffer, nucleic acids in buffer)
- 2. What form of sample do you prefer? (some sort of "VTM", Buffer)
- 3. What sample volume do you use in a single measurement?
- 4. What range of copies/uL fits your measurement range?
- 5. Is there a minimum number of "copies" you need for your test?
- 6. What test are you running? (e.g., LDT or commercial product)

Sample Providers

- 1. How many different materials do you want to provide?
 - a. are these different materials, or are they different levels of the same material?
- 2. Are you able to provide multiple levels of your material?
 - a. how many?
 - b. what levels
- 3. What is the range of copies/uL that you believe to be appropriate for this study?
 - a. (stable, homogeneous tube-to-tube)
- 4. What volume of sample will a unit contain?
- 5. What number of copies are in a unit?

Marc Salit, Ph.D. Director, Joint Initiative for Metrology in Biology — <u>http://jimb.stanford.edu</u> SLAC National Accelerator Laboratory Adjunct Professor, Departments of Bioengineering and Pathology Stanford University

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