

# CSWG Steering Committee Meeting Summary

17 April 2020

**Next Meeting: 24 April 2020 0800PDT**

Thanks to Heinz Zeichardt and Alex Marson for their presentations at this week's Steering Committee meeting — these gave us a window into emerging knowledge of assay performance in both molecular and serological testing. These talks offer a chance to see what's possible for our work and how it might support a trustworthy COVID-19 testing enterprise. These are first steps to see what it takes to develop evidence that the measurement technologies work.

## Updates

We started this week's meeting with brief updates on manuscript development and communications strategy. The manuscript on our work is coming together collaboratively (initiated with a drafting meeting on 14 April, continued on 17 April, with another planned for 20 April). The story is framed around "measurement process" diagrams annotated to make clear the key factors influencing assays (from samples to sampling devices to transport conditions to sample-extraction to assay design and configuration) to the roles of the variety of standardization methods and the different control materials being used. Heinz Zeichardt noted that our role in the enterprise is at present "Hunters and Gatherers" of the infrastructure needed to support the testing enterprise. This paper is being developed on a timeline to have a draft for organizational reviews on Monday 27 April.

The consensus communications strategy is to develop a public statement resource for each organization to use upon release of the manuscript preprint. An FAQ will also be developed and possibly hosted at SLAC or Stanford. The concept is to have decentralized communications with good resources available to all organizations to work from.

## Key Followups

- Primary focus in the upcoming week will be on developing the manuscript
  - Drafting meeting held 1400 PDT on 17 April, next one 1200 PDT on 20 April
- We'll work to develop a measurement process workflow and annotation for serological testing, parallel to the model from molecular testing
- Develop a draft annotation Minimum Information Standard about Coronavirus Control Materials

## Highlights

### **Heinz Zeichardt – Interim Evaluation of EQA Results**

Heinz presented interim results from the INSTAND interlab test, which are now released broadly to the participants. Heinz reported analysis of results from 112 of 484 participating labs. Three samples of the 7 were unblinded, and the classifications of two dilutions (1000x apart) of SARS-CoV2 “Positive” samples were 100% correct, and the classifications of the unblinded non-SARS coronavirus CoV OC43 were overall 93.8% correct (197/210) as being negative for SARS-CoV2 (these errors are false positives). These samples were inactivated, cultured virus. These were overall encouraging results, but questions remain regarding reproducibility of PCR signals, kit- and assay-specific performance, the effect of gene selection for assays, and a more thorough consideration of the effect of viral load on performance. The letter accompanying release of the interim results to participants is posted on our Slack, along with Heinz’s slides. The letter includes a thoughtful discussion of the context that led to the release of interim results while the study is open for submissions until April 28.

### **Alex Marson on first results from direct comparison of serological tests**

Alex Marson from UCSF presented a study evaluating performance of serological tests with a carefully-composed set of 270 patient samples that includes meaningfully selected positive and negative samples. Positive samples were patients who were positive by nasopharyngeal PCR tests, and negative controls were both pre-2018 samples and recent febrile symptomatic patients who were negative by nasopharyngeal PCR. Results from 10 serological tests were presented, with encouraging results for IgG. A single patient negative by PCR tested with high reactivity against most of the serological tests, and we could infer that patient was likely a false negative by PCR.

The results of these first comparisons are promising, and as a Standards Working Group, we can likely learn from the design of the study, and the sample set. We might directly use such a sample set as a model for a standard, taking into consideration the bias to highly symptomatic patients as the sample set.

Alex confirms that a preprint of this work is expected to be made available this coming week. This advance in evaluating performance of serological testing is timely, with wide interest in broad adoption of serological testing. Our WG has an opportunity to contribute in the standardization process.