

# 15 May 2020 Coronavirus Standards Working Group SC meeting Summary

---

## Next meeting 22 May 2020 0800 PDT

- Clare Morris and Mark Page from NIBSC will present a roadmap to a WHO standard for SARS-CoV-2.
- Follow-on discussion of a CSWG Collaborative Interlab Study.

Thanks as always for everyone's engagement at last Friday's Steering Committee meeting. This summary is an open document — please share this with any who might be interested, and please continue to reach out to relevant partners and stakeholders inside and outside of your organizations. This document and the slide decks from the presentations at the meeting are available in our Slack workspace (steering-committee channel) and on the JIMB website at <https://jimb.stanford.edu/covid-19-standards>. All meeting summaries and slide decks are archived there as well.

Our meeting last week had two terrific and exciting presentations —

- Rick Nolte from MUSC, representing AMP and CAP as a Subject Matter Expert, offered us a "View from the Trenches" of testing, with his experience of having tested 27000 patient samples (~1000 positives) since testing began in March.
- Heinz Zeichardt presented the results from the first interlab study of molecular testing for SARS-CoV-2, with analysis of results from the 463 labs reporting (of 487) from 36 countries.

## Interlab Study Proposal

An announcement of the 1st meeting to discuss the proposal for an interlab study constituted our preliminary business. This meeting was scheduled for Monday 18 May at 1000 PDT, and was conducted. Slides for that meeting, the meeting transcript (thanks Zoom!), and a link to the recorded meeting are posted in the Slack #interlabstudy channel.

We will have a discussion of that meeting and plans for follow-up at our 22 May SC meeting.

## Highlights

### Rick Nolte

Rick Nolte of MUSC did an off-the-cuff discussion of his experience leading testing in South Carolina. They are presently testing across the state, and all who are symptomatic or interested in being tested can. Testing includes mobile collection sites, and they are collecting ~2000 samples per day. There is varying prevalence in SC, with some parts of the state as high as 16% positive tests, and the Charleston area at a moderate 2-3%.

They have 8 platforms deployed and are constantly validating and cross-validating. They've had to continuously pivot to new platforms as supply chains come and go for every aspect of the tests, from sampling through assay. There was lively discussion of the supply chain factors, including allocation policies of both the vendors and the government. There were also significant challenges with bad materials in the supply chain, including non-sterile sampling kits. These problems are expensive and slow the whole machine down.

**Rick noted that the absence of a set of reliable reference materials was a significant barrier. When asked what he wished he had in January, he replied "A Reference Material that covered the whole assay. Genomic and spike-in RNA didn't work, weren't sufficient."**

Rick also noted that this experience is not unique but is the case for all labs.

The group had a quick discussion of alternate anatomical sampling sites and possibilities to validate them, and Rick's experience with initial work to validate saliva samples against NP swabs suggests we might have useful work to do as a group here, though there wasn't confidence expressed in FDA guidance for doing so.

#### **Heinz Zeichardt, Martin Kammel, and Hans-Peter Grunert**

Heinz and his colleagues Martin Kammel and Hans-Peter Grunert together represented INSTAND and presented the results from the "Extra INSTAND EQA Scheme (340) - April 2020 Virus Genome Detection SARS-CoV-2" study. This first study of its kind had 487 participants with results returned from 463 of them.

Heinz, Martin, and Peter's slides are posted on the Slack workspace and the JIMB website.

Three samples were unblinded in early May, and results on the 4 remaining samples were presented on Friday, including the lowest concentration positive sample, which had 93% correct results (sensitivity). The non-SARS-CoV-2 samples (specificity controls) had 98.6% and 97.3% (after transcription error correction!) accurate calls.

Analysis of the reported Ct/Cp/Cq values show promise for harmonization through calibration, which is sure to be a topic of our WG discussion and work as we continue.

Heinz has already announced follow-on molecular & serological EQA schemes to come (also announced on our Slack workspace).