

4 September
2020

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SLAC National
Lab and Stanford
University

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



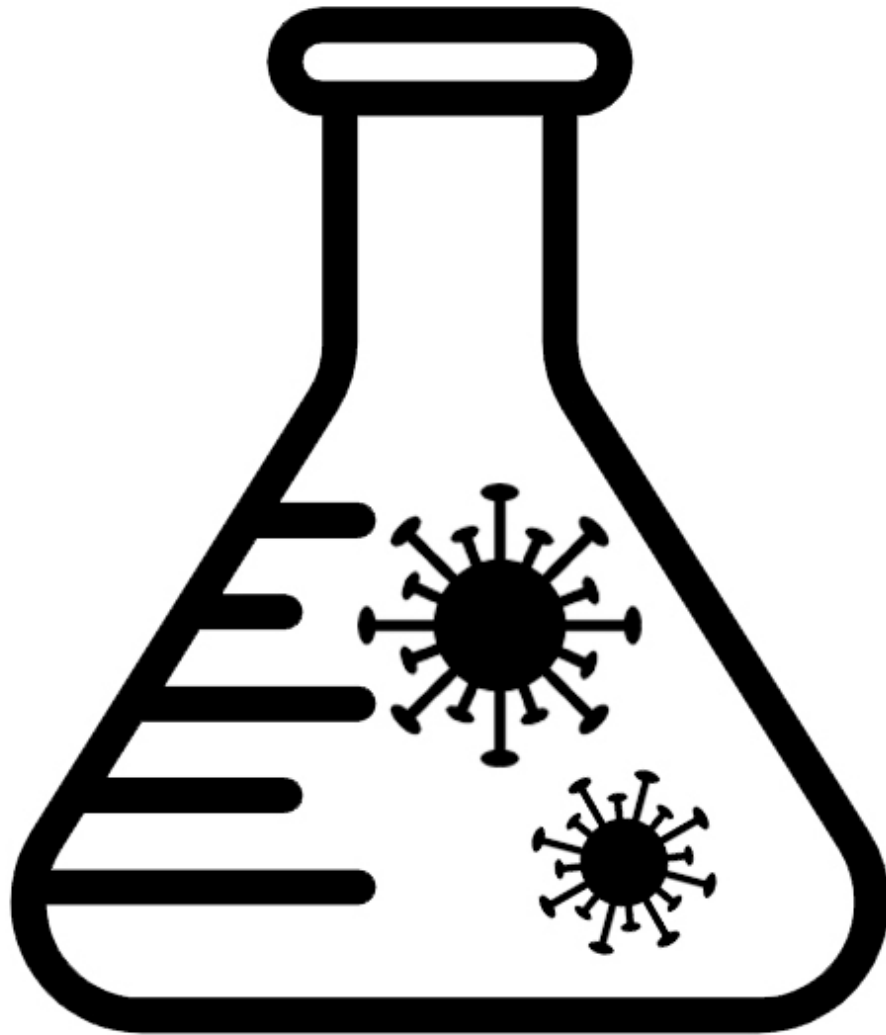
Identify and develop critical infrastructure to support...

- confidence in test results
- interoperability
- scale-up
- long-term capacity



Identify best practices that should be institutionalized

Learn what we need to so next time we have a global network in place ready to make standards.



21 August Agenda

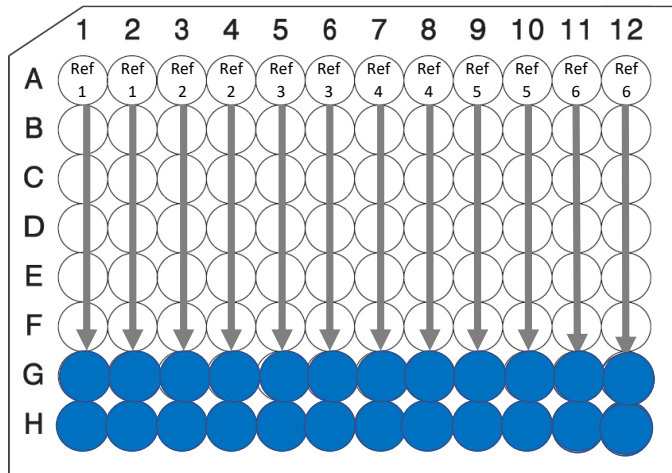
- CSWG Products: Harmonization Kit, Benchmarking Kit, Validation Kit
 - John Sninsky, Tom White, Marc Salit
- Adding signal to the noise: Perspectives & Communications
 - Harmonizing references used in regulatory oversight
 - What tests, when, and for what?
 - Testing in support of Vaccine Development



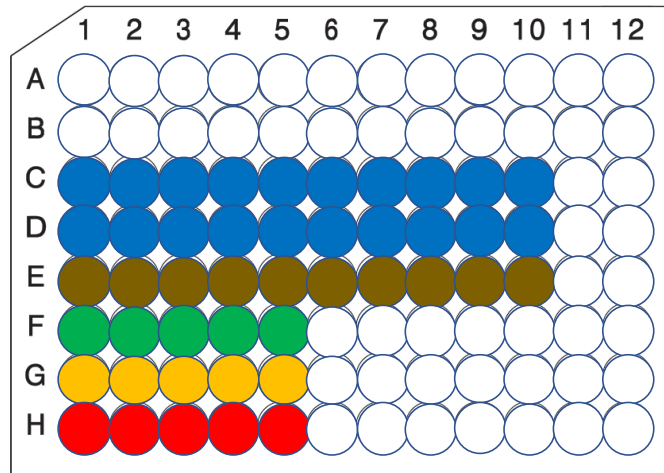
Putting the “Standards” in the CSWG

John Sninsky, Tom White, Marc Salit

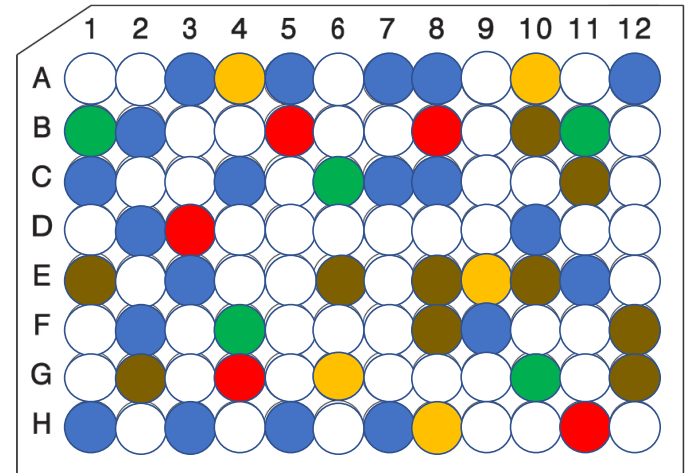




Harmonization Kit

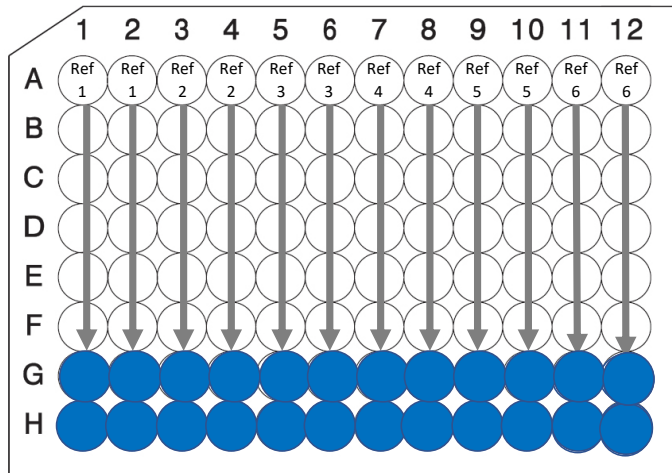


Benchmarking Kit

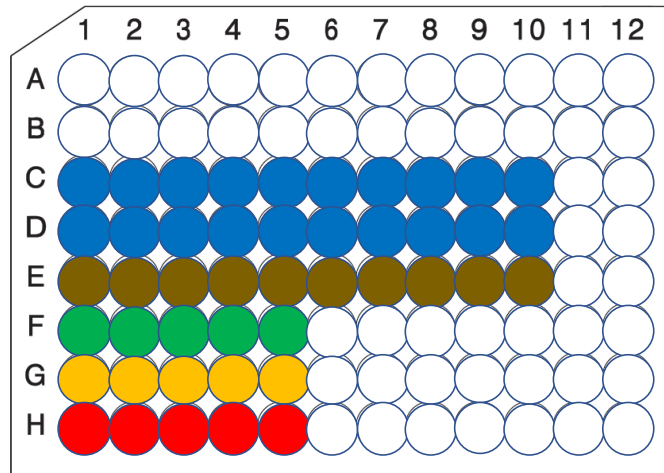


Validation Kit

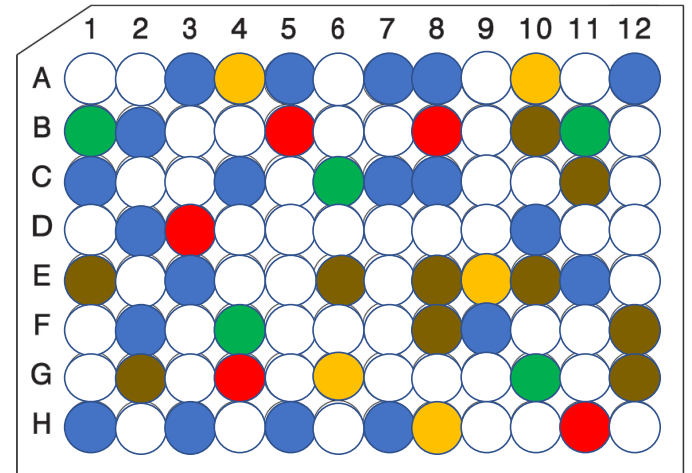
3 Kits for SARS-CoV-2 Viral Standards:
 “Quality Materials”



Harmonization Kit



Benchmarking Kit

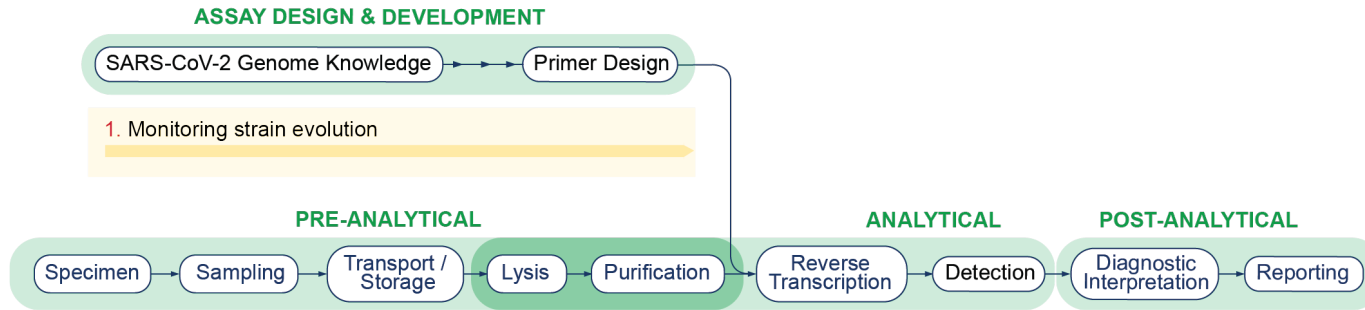


Validation Kit

Refinements:

viral surrogates & nucleic acids

harmonization from undiluted materials



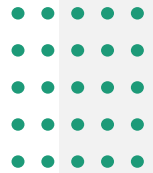
CONTROL MATERIALS

- 2. SARS-CoV-2 Run Controls:
Clinical samples / cultured virus / viral like particles
- 3. SARS-CoV-2 Nucleic Acid Positive Controls:
Viral RNA / Synthetic RNA *Viral cDNA / Synthetic cDNA*
- 4. Non-SARS-CoV-2 Internal Controls:
Human RNA *Non-SARS-2 Virus* *Non-SARS-2 Nucleic-Acid*
- 5. Controls for False Positives :
Negative samples / mock samples

Molecular Testing is a Measurement Process

Standards and controls work in different parts of the process

Quality requires controls for each process element



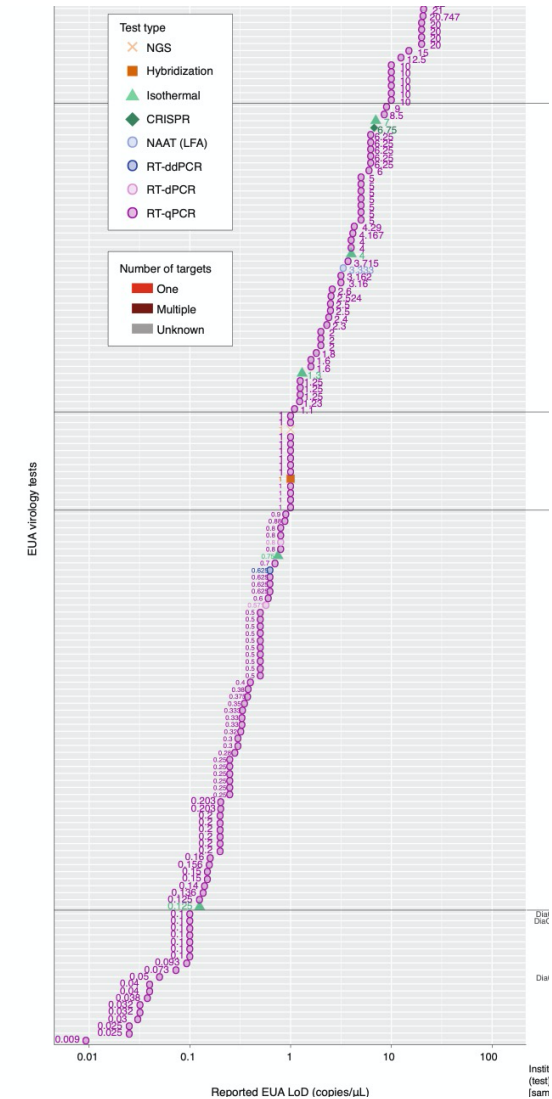
How we can help coordination, and how that might make a difference.

- Reference control set and performance assessment kit
 - Improve accuracy for intended use
- Testing Performance Dashboard
- Can an integrated testing performance platform inform policy?
 - Load Balancing – Smart Testing Grid
 - Integration of tacit knowledge
 - Supply Chain knowledge
 - Improve test frequency and turn-around-time for reporting results

Let's describe this plan in a publication *(draft linked in the invite)*

- EUA Approvals NOT comparable leading to inaccurate interpretation of tests
- Harmonized reference samples will enable meaningful comparison
- We recommend an EUA for reference samples that will be used for Test EUA

MacKay, M.J., Hooker, A.C., Afshinnekoo, E. *et al.* The COVID-19 XPRIZE and the need for scalable, fast, and widespread testing. *Nat Biotechnol* **38**, 1021–1024 (2020).
<https://doi.org/10.1038/s41587-020-0655-4>



A dark blue, irregularly shaped graphic with a splatter effect, containing white text. The graphic is centered on a white background and has a rough, hand-painted appearance with some lighter blue and white speckles around its edges.

Stopped Here on 4
September