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

viral surrogates & nucleic acids
harmonization from undiluted materials
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

Stopped Here on 4 September