

11 September
2020

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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



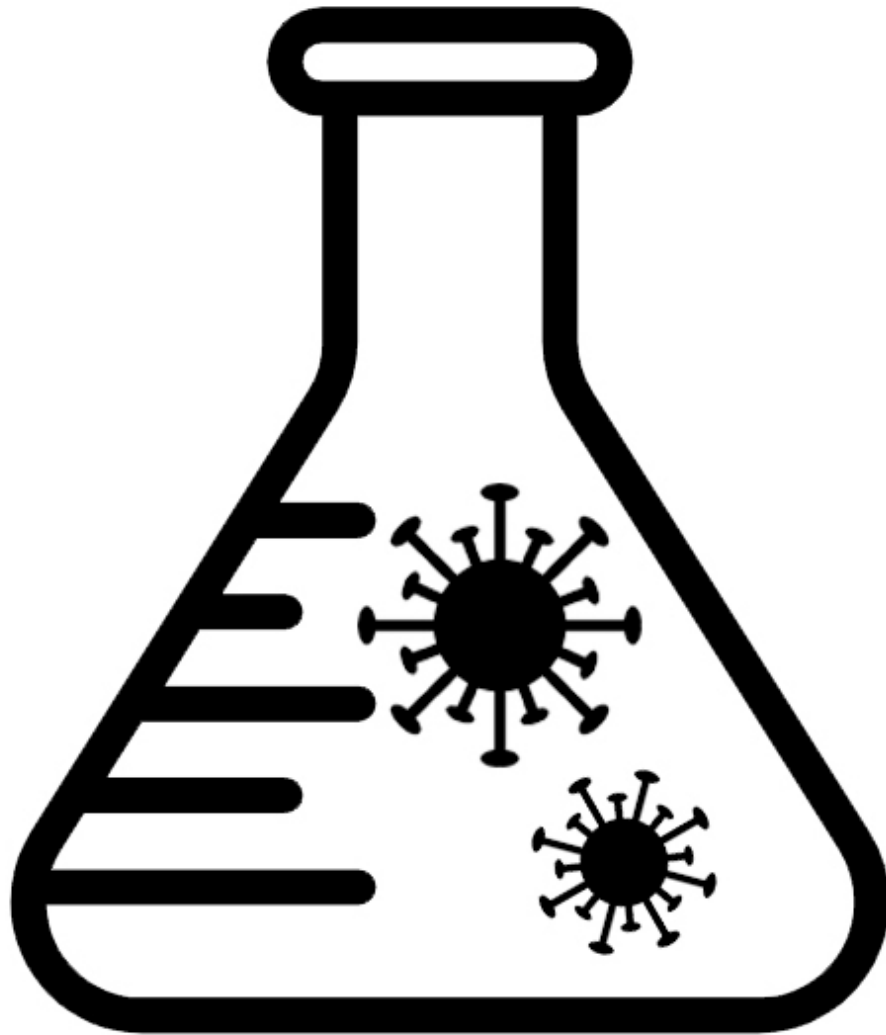
Identify and develop critical infrastructure to support...

- 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.



11 September 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



We can make the standards to make molecular testing robust, reliable, and quantitatively comparable.



‘Harmonization Kit’ to establish comparability of a set of standards to put molecular testing results on a common scale

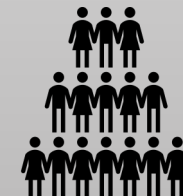
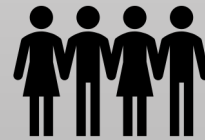
“Benchmarking Kit” for turn-key evaluation of molecular testing platforms

“Validation Kit” for blinded validation with a dashboard to form a “smart-grid” for testing

just a few labs, NMIs

test developers

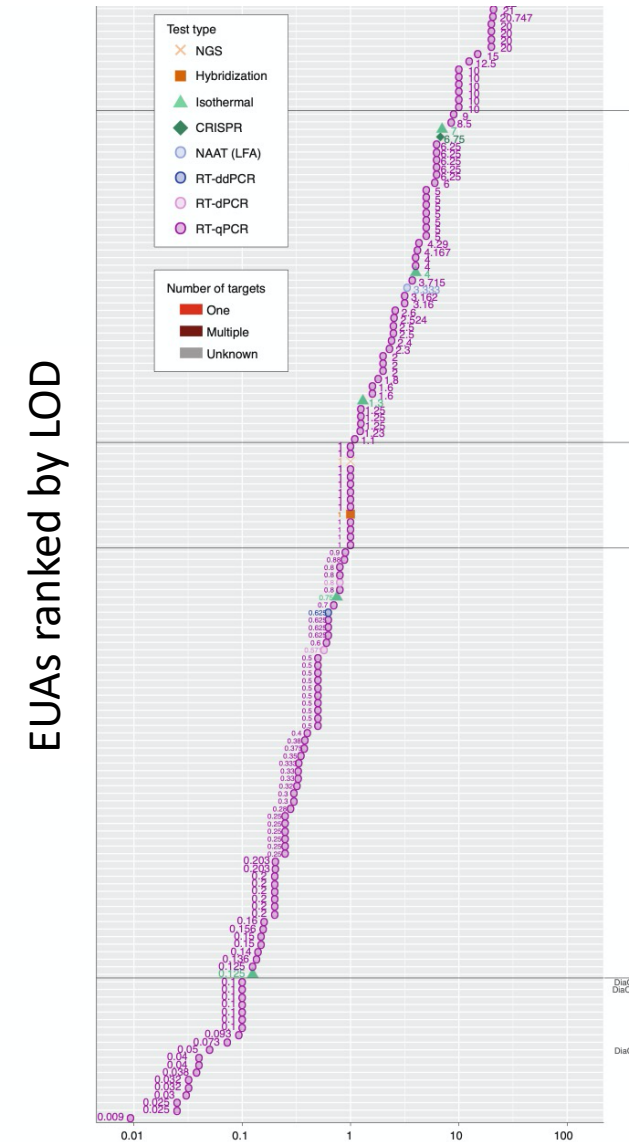
routinely measured at testing labs



Let's describe this plan in a publication and make a policy recommendation

- EUA Approvals are NOT comparable
 - leading to inaccurate interpretation of tests
- Harmonized reference samples will enable meaningful comparison
 - right now nobody knows (including regulators) if tests are different, or if test performance changes, because we don't have calibration materials with metrological traceability to a common reference
- We recommend an EUA for reference samples that will be used for Test EUA

Figure from MacKay, M.J., Hooker, A.C., Afshinnkoo, 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->



LODs from EUA Applications
vary over 4 logs