17 April 2020

Marc Salit,
JIMB Director

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

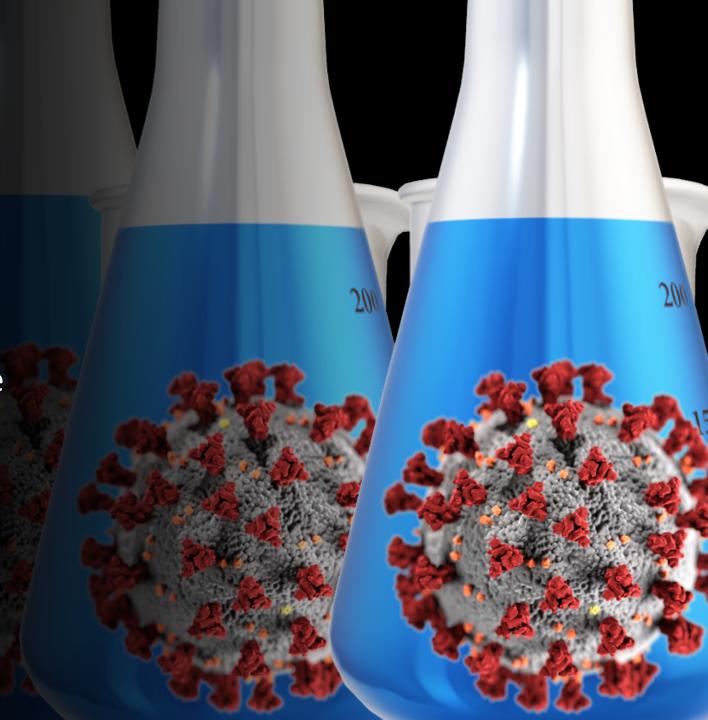


Identify best practices that should be institutionalized

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

### 17 April Agenda

- Manuscript update
- Communications Strategy update
- Early results from comparisons
  - Heinz Zeichardt, IQVD GmbH
    - INSTAND EQAS 340
  - Alex Marson, UCSF
    - Serological Benchmarking

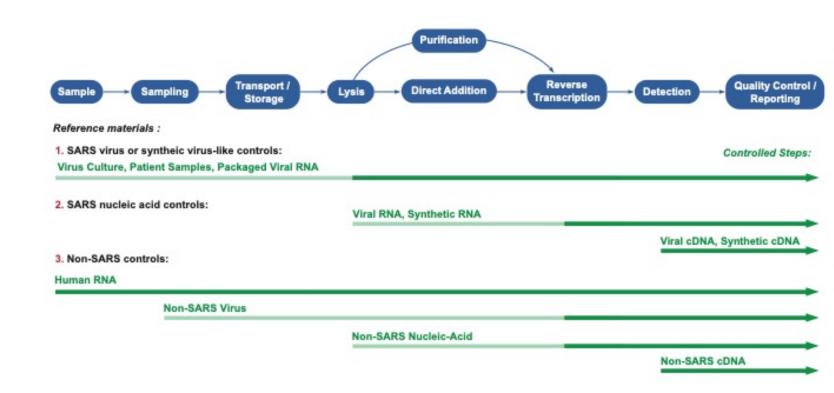


# Manuscript Update

"We are working together to make sure that the standards, controls, validation tests, and protocols are in place so we can count on test results.

Our work is foundational, and upstream of the existing mechanisms that establish reliability and trustworthiness of results in the diagnostic sector, including regulatory oversight.

This report describes our systematic consideration of the measurement process and how different standards play roles throughout it."



## Communications Strategy Update

#### Follow-up from Last Week

- Compiling list of communications avenues
- Considered name
  - Standardization
  - International
  - Global
  - "Working Group" implies action
  - Acronyms
  - Scope
    - "Emerging virus..."
    - "COVID"

#### Near-term Plans

- Develop and roll out preprint
- Coordinate network of communications from the WG
  - provide high-level messaging about the WG and the findings in the preprint
  - use all member's audiences, channels, vernaculars
  - develop FAQs
  - press/media outreach (Nature, GenomeWeb, quality news papers,...)

# Early results from an interlab study

Prof. Dr. Heinz Zeichhardt IQVD GmbH Institut für Qualitätssicherung in der Virusdiagnostik Berlin



#### INSTAND e.V.

Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e. V. (vormals Hämometerprüfstelle)

Extra INSTAND EQAS –Virus Genome Detection (340)

In cooperation with

Coronavirus SARS-CoV-2

Deadline for registration:

Deadline for receipt of data:

Shipment:

Dear colleagues.

Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (DVV)

Sunday, 29 March 2020

Wednesday, 22 April 2020

Friday, 03 April 2020

Gesellschaft für Virologie (GfV)

Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM)



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Referring to our information of 14 February 2020, INSTAND e.V. wants to inform you on the organizational changes in regard to the EQA scheme for virus genome detection of coronaviruses.

Due to the new epidemiological situation with SARS-CoV-2, INSTAND e.V. in its capacity as reference institution of the German Medical Association as EQA provider will change the EQA schemes for virus genome detection of coronaviruses

#### EQA schemes for virus genome detection of coronaviruses in the year 2020

#### EQA term April 2020 - Extra EQA scheme for virus genome detection of SARS-CoV-2

of SARS-CoV-2 (samples, which contain SARS-CoV-2 are inactivated).

The following parameters can be analyzed in this EQA scheme applying commercial and in house test systems:

SARS-CoV-2 (RNA) - quantitative

This extra EQAS will focus on the virus genome detection Participating at these EQA terms give the option for differentiation between SARS-CoV-2. MERS CoV and other human coronaviruses (samples which contain the SARS-CoV-2 and MERS CoV, respectively, are

EQA terms summer 2020 and November 2020 - EQA scheme

for virus genome detection of coronaviruses incl. SARS-CoV-2

23 March 2020

The following parameters can be analyzed: SARS-CoV-2 (RNA) – quantitative SARS-CoV-2 (RNA) – qualitative

#### Alex Marson

Associate Professor, UCSF Scientific Director of Biomedicine, Innovative Genomics Institute (IGI) Chan Zuckerberg Biohub Investigator

# Early results from a serological test comparison

Compare a large population of serological tests using a well-designed panel of ~300 patient samples

# All other business

Mailing list – converting to Google Groups (MailChimp too much work) Communications, planning, engagement, process, operations?

# Discussion