SARS CoV-2 Test Performance Update

Frances Pouch Downes, DrPH

Professor, Michigan State University

Opinions expressed in this presentation are those of the speaker and do not express the views or opinions of Cardinal Health

Learning Objectives

Describe the laboratory methods used for SARS CoV-2 testing.

Explain the role of proficiency testing in a laboratory quality management system.

Describe the participant, methods and results of multiple SARS CoV-2 RT PCR proficiency testing results.

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Role of SARS CoV-2 Testing

Diagnosis of infection	Treatment and medical management Isolation
Case finding and contact tracing	Control further transmission
Surveillance	Distribute resources Evaluate policies

https://www.mlive.com

SARS CoV-2 Tests

RNA

- RT PCR and other Nucleic Acid Amplification methods
- Detects current infection
- Performed in high complexity lab, TAT hours to days
- Genotyping for surveillance

Antigen

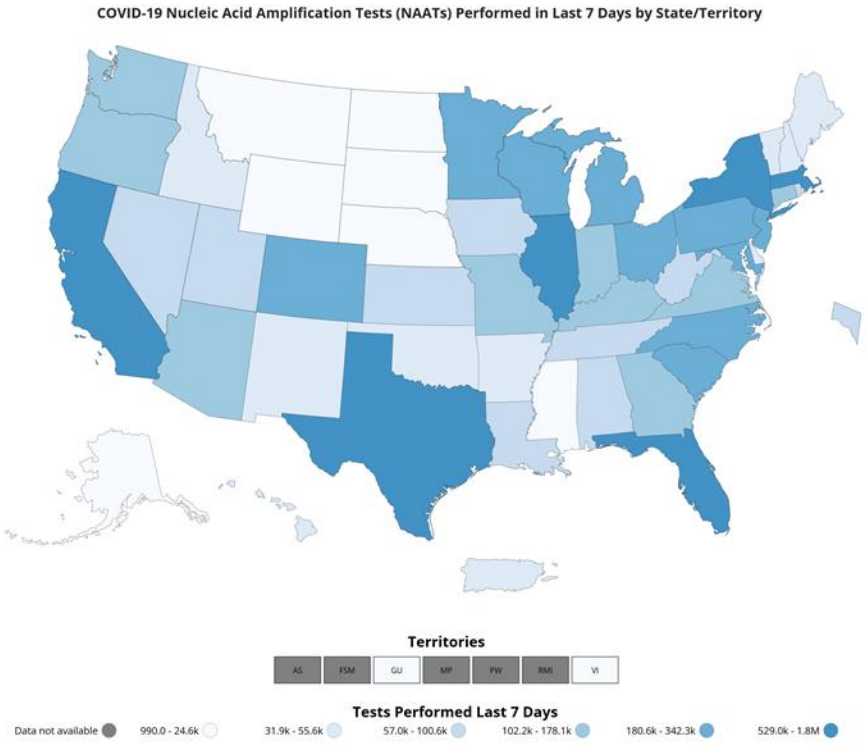
- Solid Phase EIA and other methods
- Detects current infection
- Rapid, on-site

Antibody

- EIA, bead-based ab detection, *etc.* detection methods
- Detects current or past infection
- Performed in a variety of testing settings from high complexity lab to waived

SARS CoV-2 RNA Testing Landscape

- 590,249,882 US RNA tests reported
- 45,666,109 positive
- 262 nucleic acid tests, pooling protocols or collection devises approved FDA

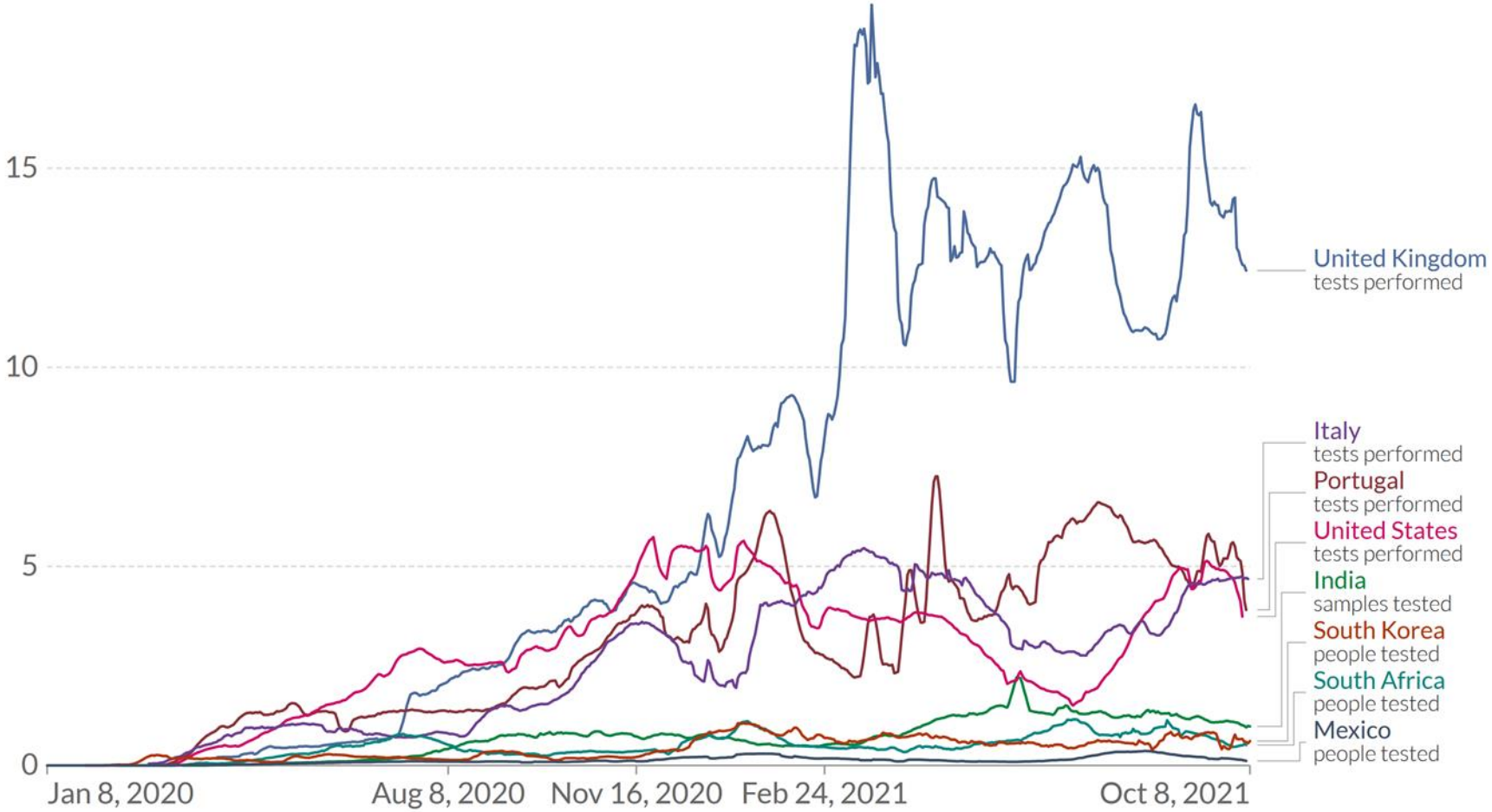


https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2

https://covid.cdc.gov/covid-data-tracker/#cases_tests7day

Daily COVID-19 tests per thousand people

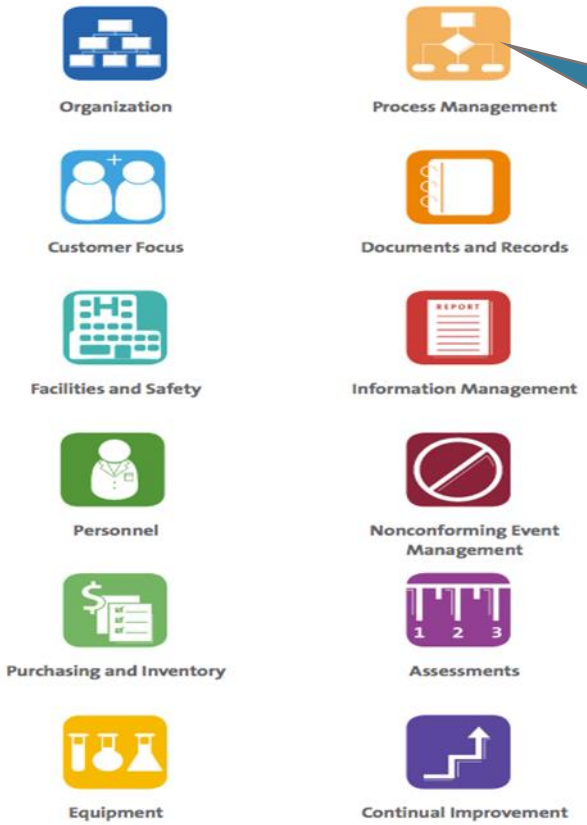
The figures are given as a rolling 7-day average.



Source: Official data collated by Our World in Data – Last updated 8 October 2021, 10:20 (London time) OurWorldInData.org/coronavirus • CC BY
Note: Comparisons of testing data across countries are affected by differences in the way the data are reported. Daily data is interpolated for countries not reporting testing data on a daily basis. Details can be found at our Testing Dataset page.

https://www.chieftain.com/story/opinion/cartoons/2020/08/07/granlund-cartoon-covid-test-accuracy/114172988

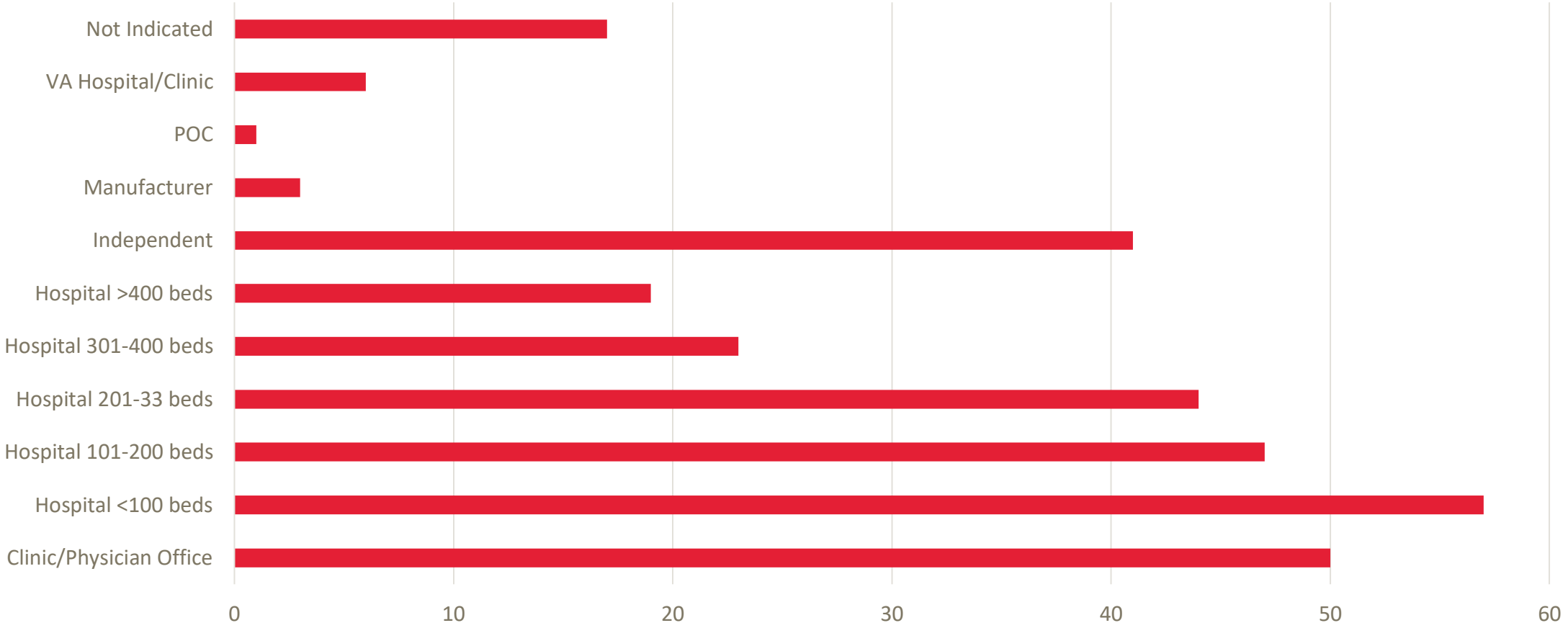
Quality System Essentials



Source: CLSI.org

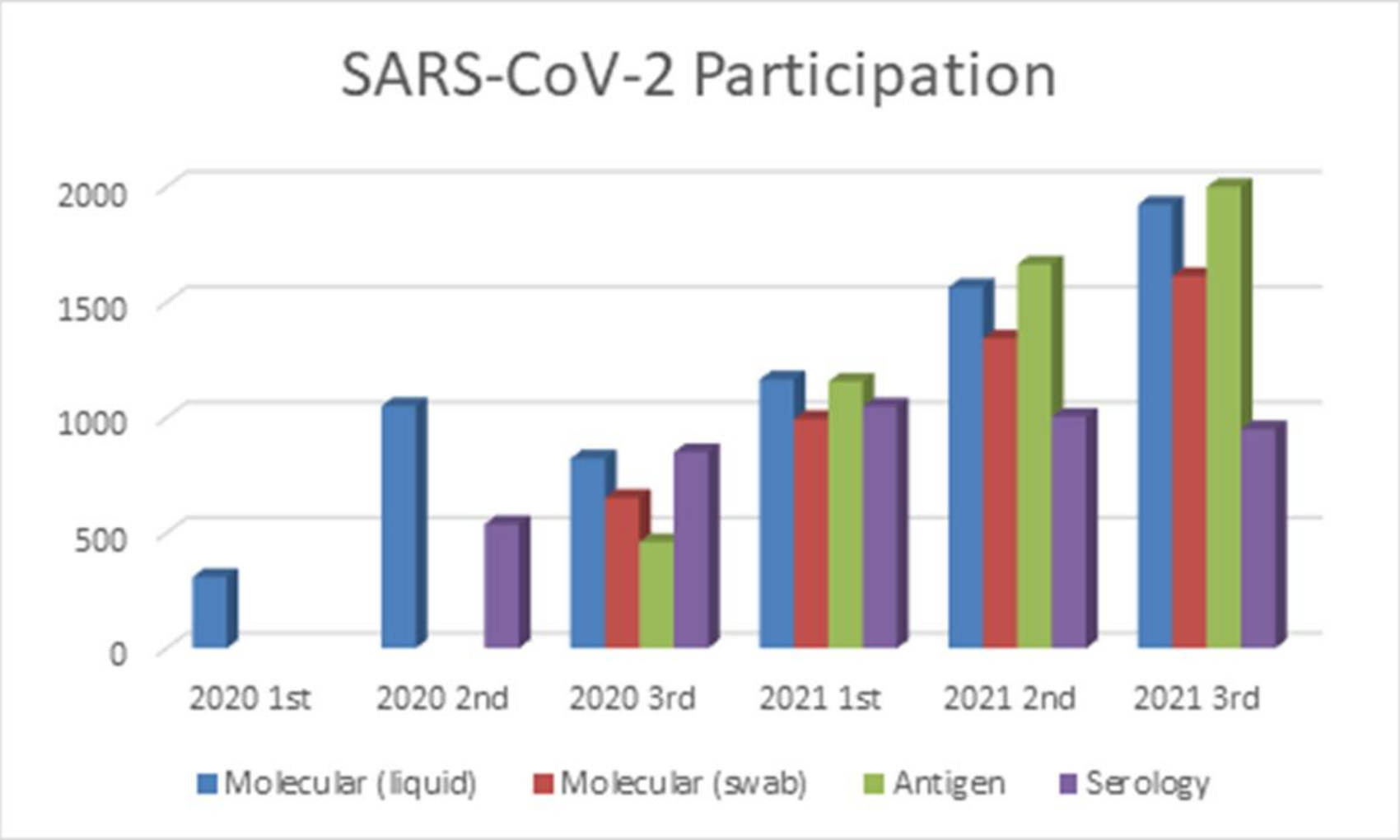
- Method verification and validation
- Equipment calibrations
- Pre-examination processes
- Quality control
- Proficiency testing
- Reporting results/post-examination processes

RNA Methods: Participant Laboratories



Source: Edson, D. *et al.* 2020 . Am J Clin Path 154(4)

API: Provider of 4 SARS CoV-2 Proficiency Programs



Source: Casey, API

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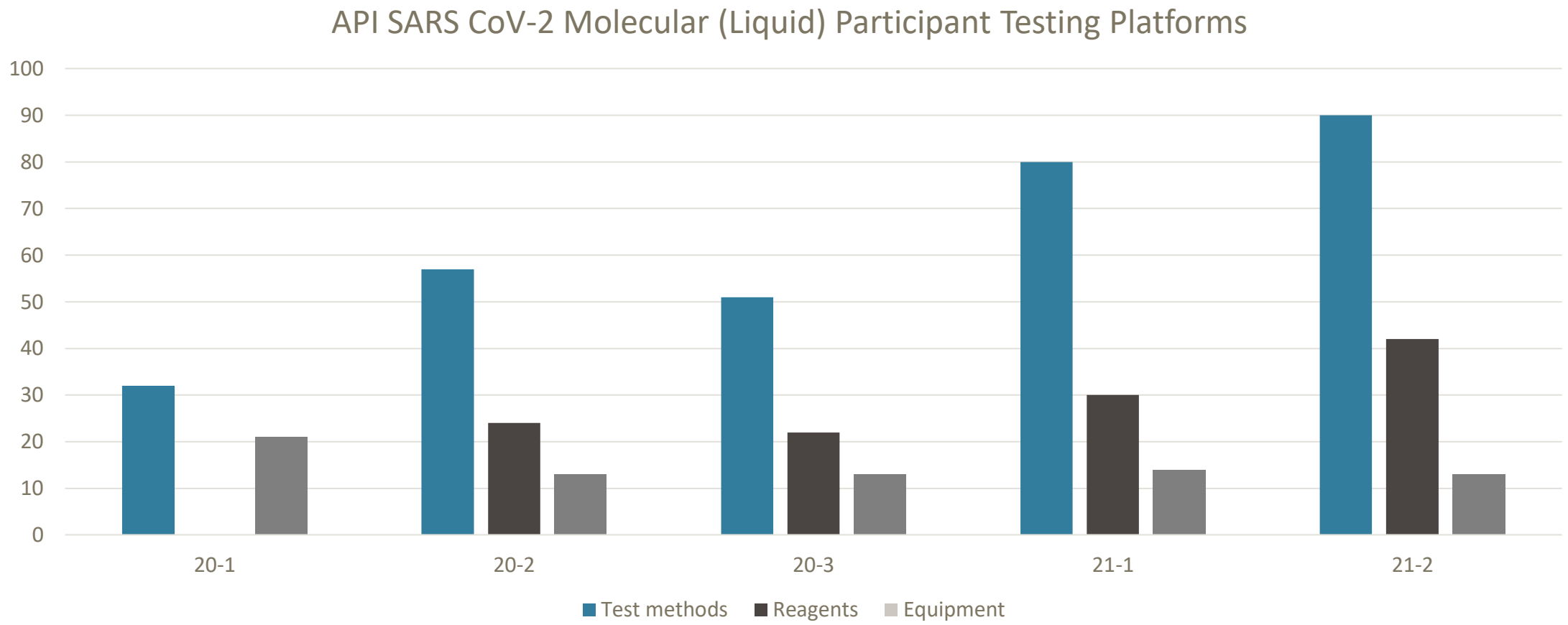
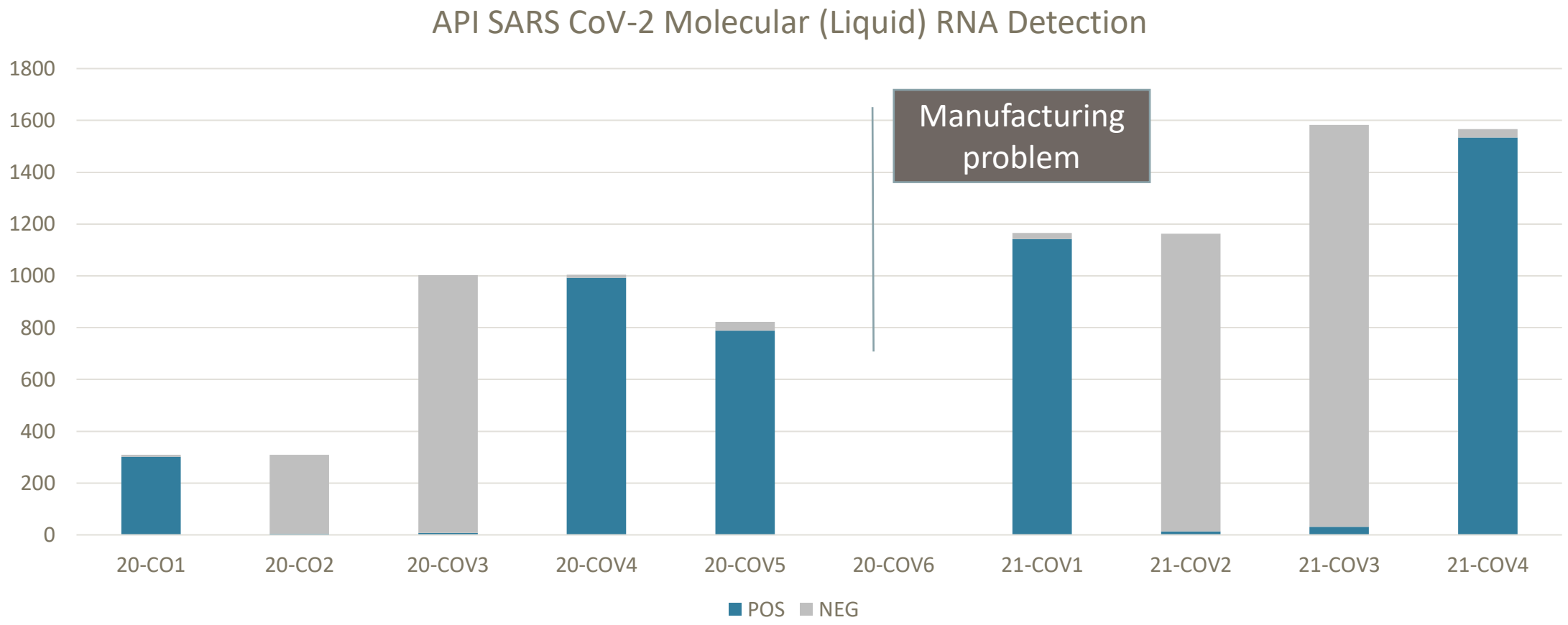
RNA Methods: Platforms



RNA Methods: Results

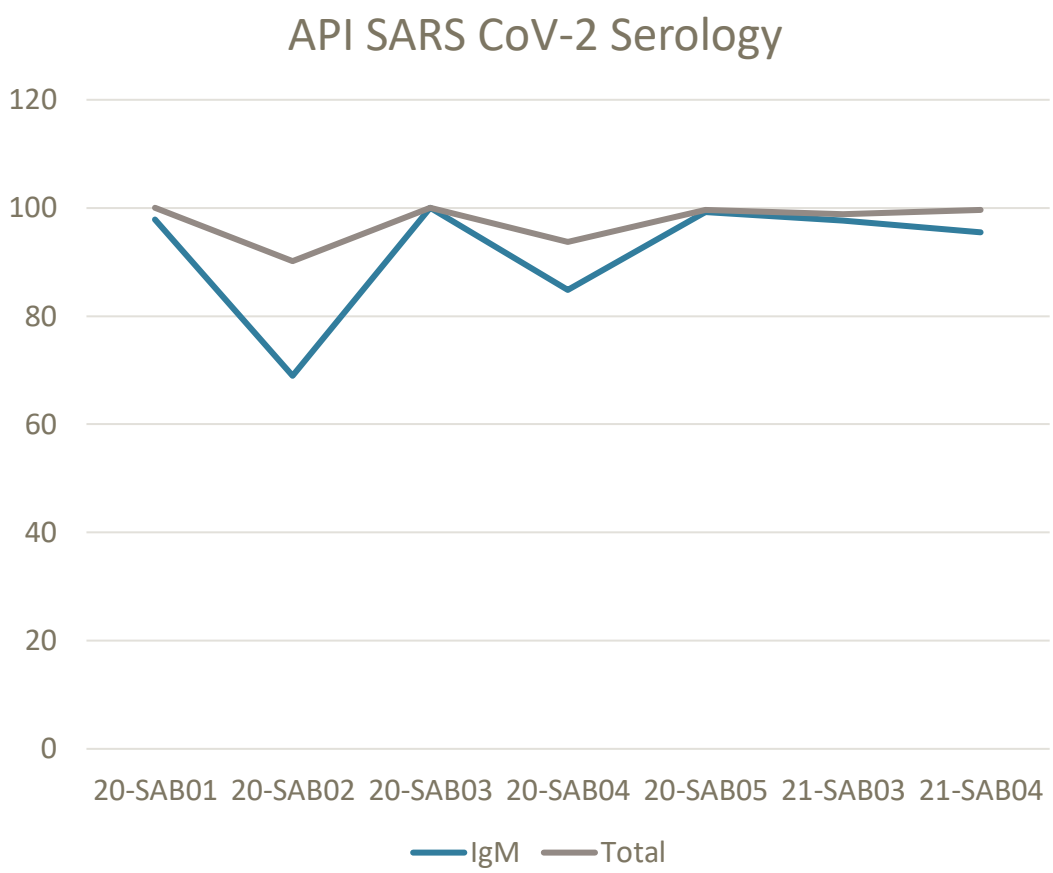


RNA Methods: Conclusion

- NAAT testing results are reliable
  - Performance on both the liquid and swab-based PT samples are consistently >98%
- Increasing number of laboratories involved in testing
- Increasing number of methods with FDA EUA
- Increasingly users enroll in the wrong program

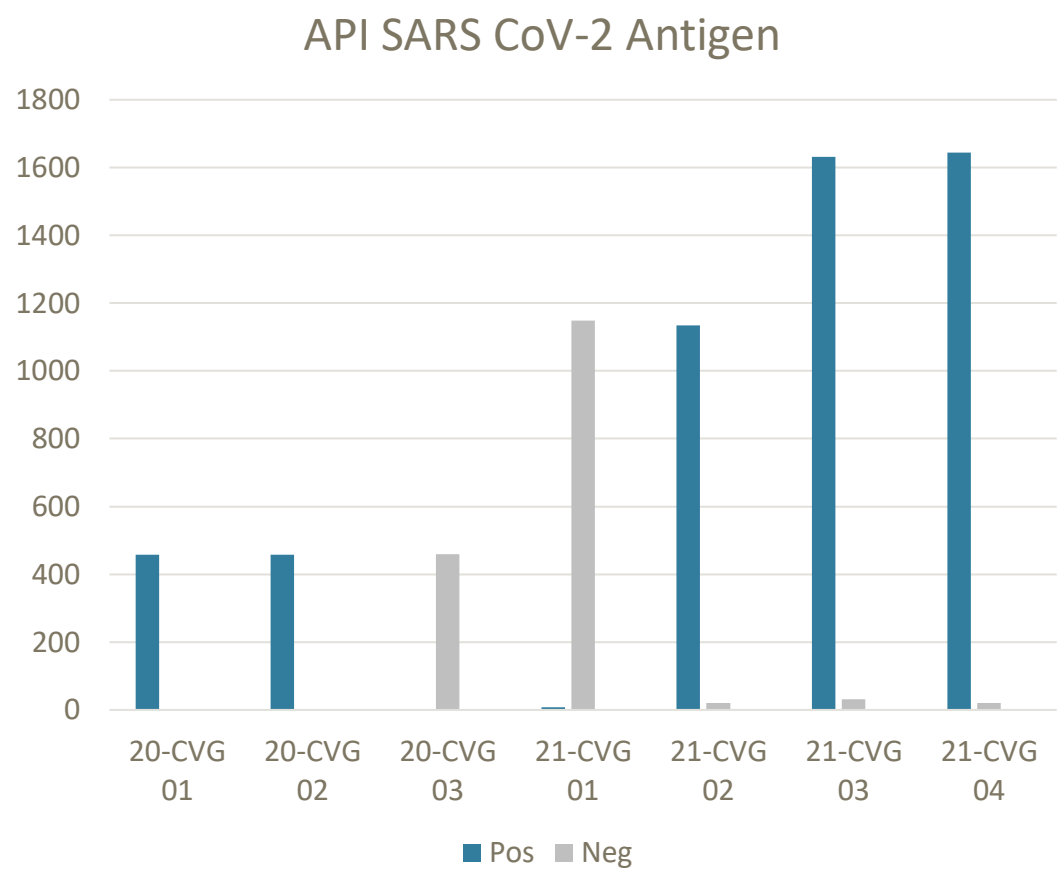
Antibody Methods Performance

- Lack of international standard
- 5 events
- Participants peaks at 1049, declining to 950 (2021-3rd)
- IgM (65-100%) agreement is more challenging than IgG



Antigen Method Performance

- Analyte quantifiable
- 3 events reported
- 461 climbing to 2047 (2021 event 3) participants
- Approximately 98% agreement with target value
- 9 participants enrolled in wrong program



Discussion

- Multiple global PT providers
- Clerical errors included in performance
- Enrollment in the wrong program

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Thank you