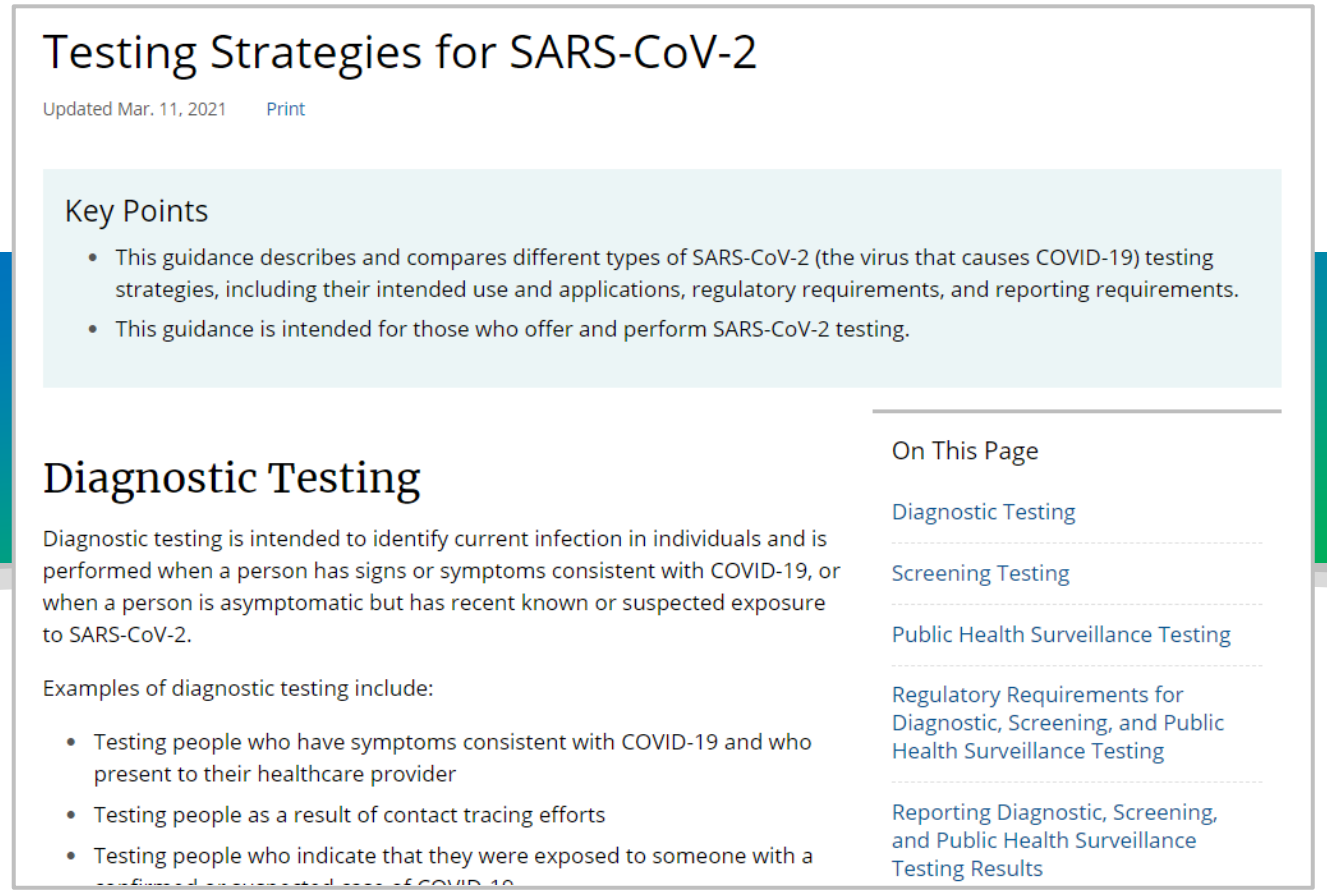
Clinical Laboratory COVID-19 Response Call

Monday, March 22, 2021 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, Division of Laboratory Systems, CDC
- **SARS-CoV-2 Variants Update**
  - Vivien Dugan, CDC Laboratory and Testing Task Force for the COVID-19 Response
- **COVID Detect: Longitudinal Comparison of Multimodal CoV Test Results with Live Virus Shedding**
  - Christopher Brooke, University of Illinois
  - Rebecca Smith, University of Illinois
- **CMS Update**
  - Monique Spruill, Centers for Medicare and Medicaid Services (CMS)
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

Testing Strategies Update

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/sars-cov2-testing-strategies.html



Testing Strategies for SARS-CoV-2

Updated Mar. 11, 2021 Print

Key Points

- This guidance describes and compares different types of SARS-CoV-2 (the virus that causes COVID-19) testing strategies, including their intended use and applications, regulatory requirements, and reporting requirements.
- This guidance is intended for those who offer and perform SARS-CoV-2 testing.

Diagnostic Testing

Diagnostic testing is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

Examples of diagnostic testing include:

- Testing people who have symptoms consistent with COVID-19 and who present to their healthcare provider
- Testing people as a result of contact tracing efforts
- Testing people who indicate that they were exposed to someone with a

On This Page

Diagnostic Testing

Screening Testing

Public Health Surveillance Testing

Regulatory Requirements for Diagnostic, Screening, and Public Health Surveillance Testing

Reporting Diagnostic, Screening, and Public Health Surveillance Testing Results

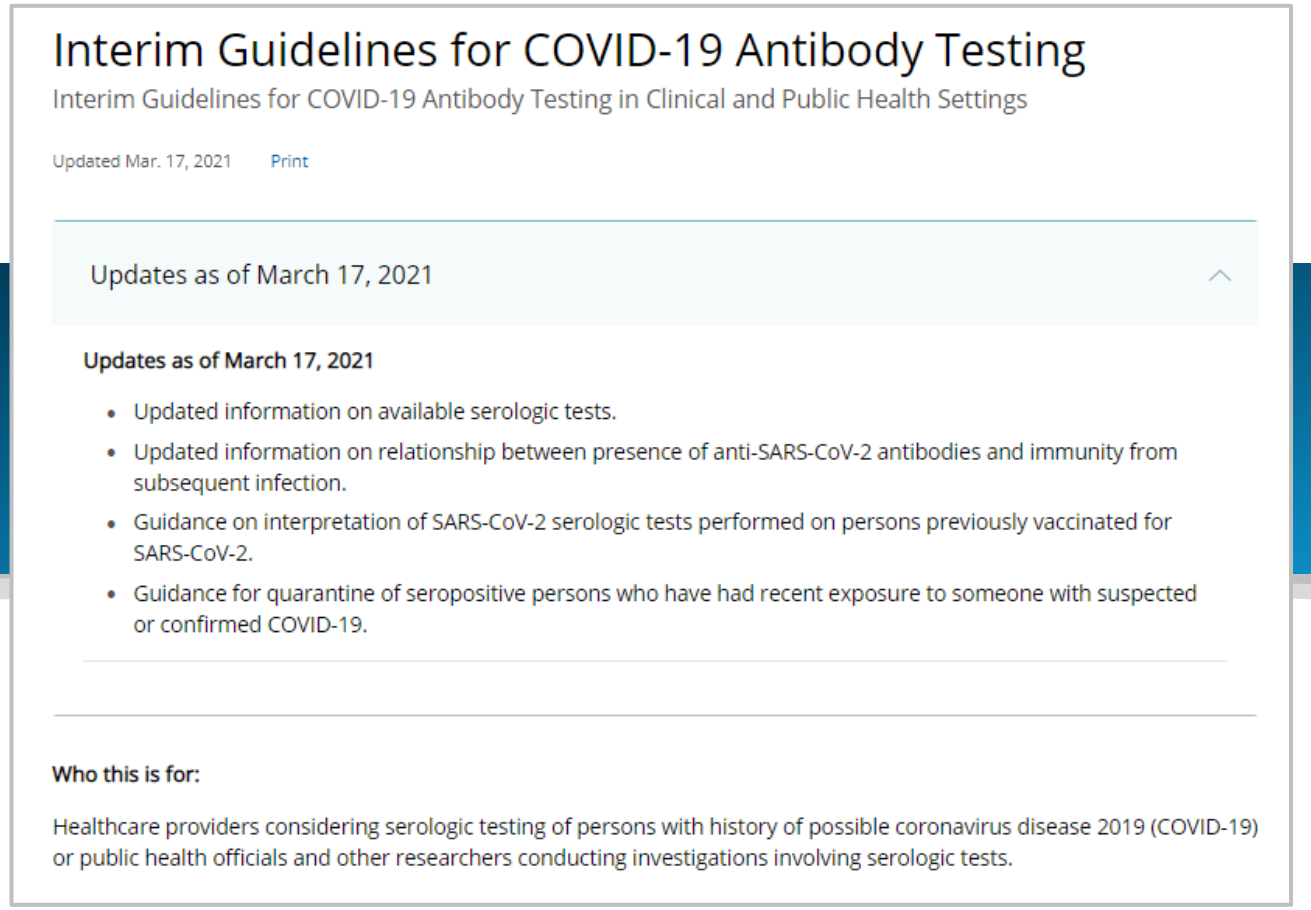
Point-of-Care Testing Update

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

Laboratories or point-of-care testing sites that have applied for a CLIA Certificate of Waiver to perform SARS-CoV-2 point-of-care testing can begin testing and reporting SARS-CoV-2 results as soon as they have submitted their application to the State Agency, as long as they meet any additional state licensure requirements that apply.

Antibody Testing Update

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html



Interim Guidelines for COVID-19 Antibody Testing

Interim Guidelines for COVID-19 Antibody Testing in Clinical and Public Health Settings

Updated Mar. 17, 2021 Print

Updates as of March 17, 2021

Updates as of March 17, 2021

- Updated information on available serologic tests.
- Updated information on relationship between presence of anti-SARS-CoV-2 antibodies and immunity from subsequent infection.
- Guidance on interpretation of SARS-CoV-2 serologic tests performed on persons previously vaccinated for SARS-CoV-2.
- Guidance for quarantine of seropositive persons who have had recent exposure to someone with suspected or confirmed COVID-19.

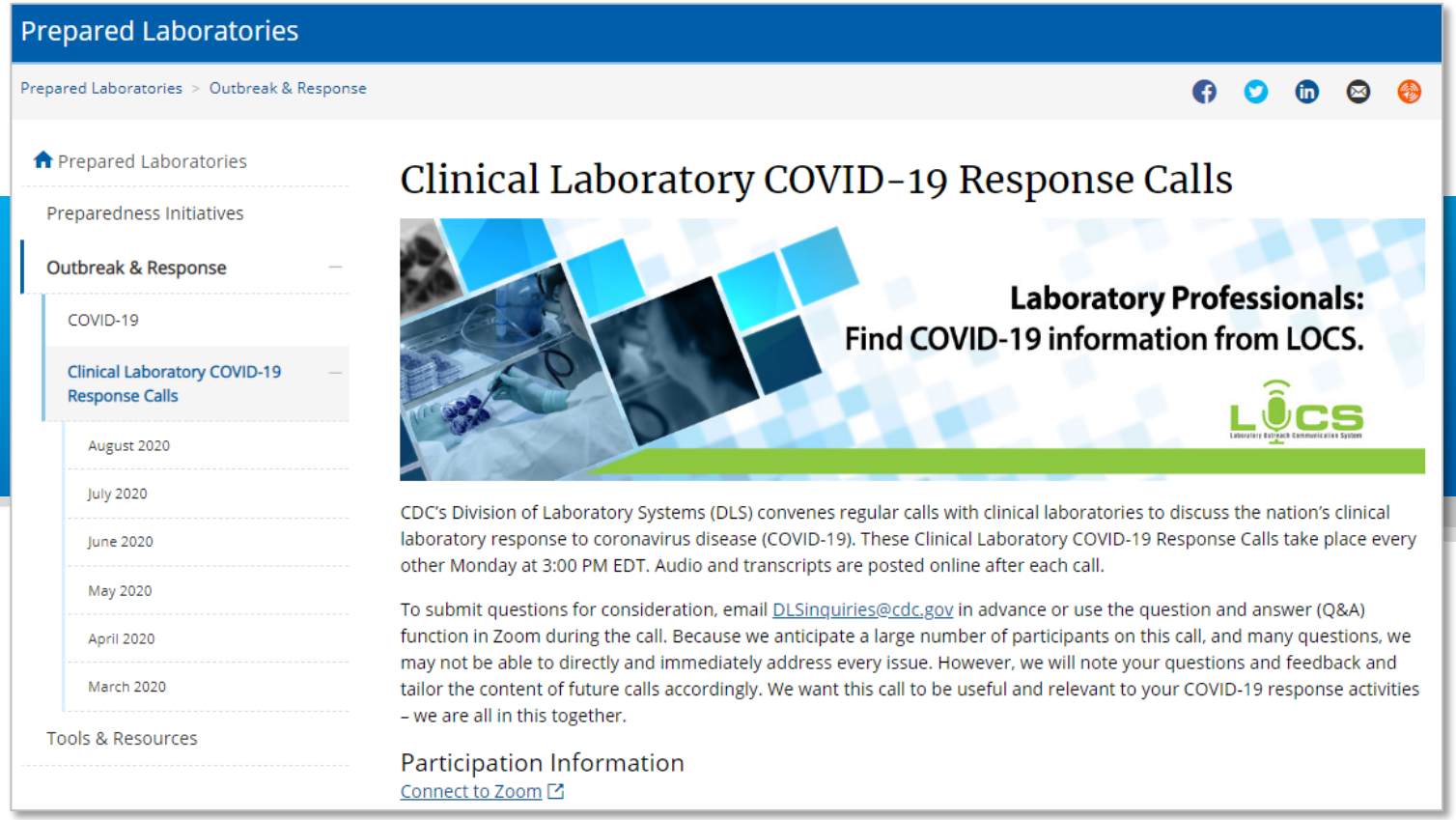
Who this is for:

Healthcare providers considering serologic testing of persons with history of possible coronavirus disease 2019 (COVID-19) or public health officials and other researchers conducting investigations involving serologic tests.

CDC Preparedness Portal

https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html

Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal



Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, April 5** from

3:00 PM to 4:00 PM EDT

We Want to Hear From You!

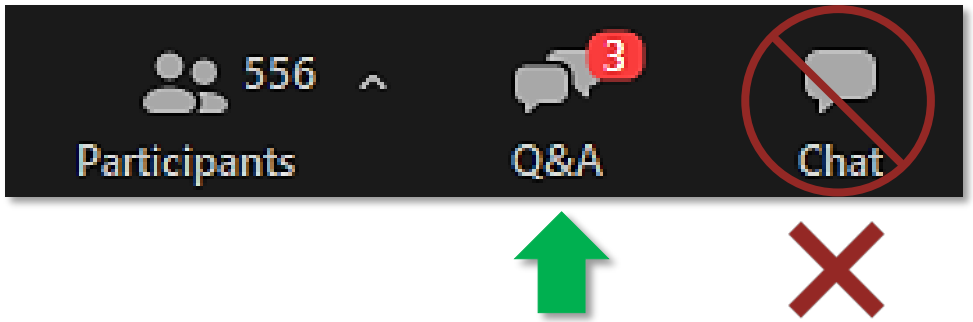
Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

How to Ask a Question

- **Using the Zoom Webinar System**
  - Click the **Q&A** button in the Zoom webinar system
  - Type your question in the **Q&A** box and submit it
  - Please do not submit a question using the chat button



- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

SARS-CoV-2 Variants Update

Vivien Dugan
CDC Laboratory and Testing Task Force for the COVID-19 Response

Variant Classifications

- Established in collaboration with the SARS-CoV-2 Interagency Group (SIG)
  - Each variant class includes possible attributes of lower classes; variant status might escalate or deescalate based on scientific evidence

- **Variant of Interest**: contains specific genetic markers associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity
- **Variant of Concern**: evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures
- **Variant of High Consequence**: clear evidence that prevention measures or medical countermeasures (MCMs) have significantly reduced effectiveness relative to previously circulating variants

SARS-CoV-2 Variants of Concern | CDC

Variants of Interest

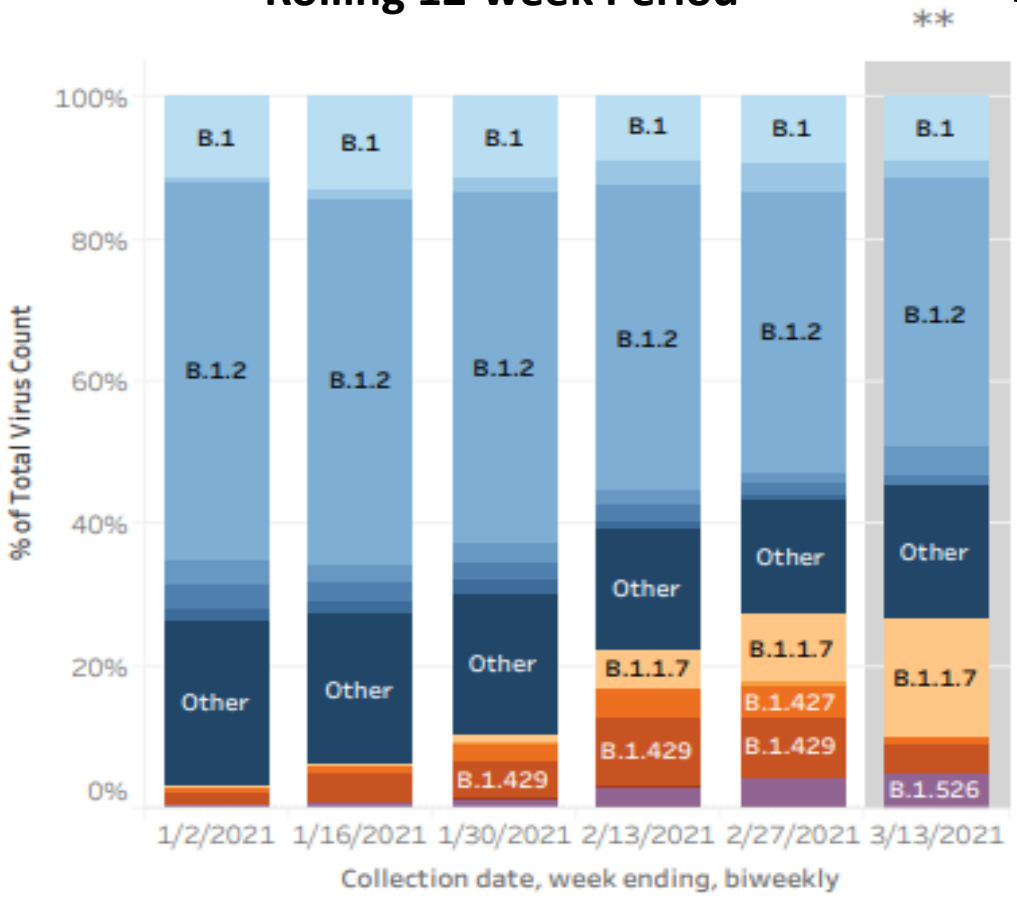
Name (Pango lineage)	Substitution	Name (Nextstrain[a])	First Detected	Predicted Attributes
B.1.526	**Spike:** (L5F*), T95I, D253G, (S477N*), (E484K*), D614G, (A701V*) **ORF1a:** L3201P, T265I, Δ3675/3677 **ORF1b:** P314L, Q1011H **ORF3a:** P42L, Q57H **ORF8:** T11I **5'UTR:** R81C	20C	New York/ November 2020	•Potential reduction in neutralization by monoclonal antibody treatments •Potential reduction in neutralization by convalescent and post-vaccination sera
B.1.525	**Spike**: A67V, Δ69/70, Δ144, E484K, D614G, Q677H, F888L **ORF1b**: P314F **ORF1a**: T2007I **M**: I82T **N:** A12G, T205I **5'UTR**: R81C	20C	New York/December 2020	•Potential reduction in neutralization by monoclonal antibody treatments •Potential reduction in neutralization by convalescent and post-vaccination sera
P.2	**Spike**: E484K, D614G, V1176F **ORF1a**: L3468V, L3930F **ORF1b**: P314L **N:** A119S, R203K, G204R, M234I **5'UTR**: R81C	20J	Brazil/April 2020	•Potential reduction in neutralization by monoclonal antibody treatments •Potential reduction in neutralization by convalescent and post-vaccination sera

Variants of Concern

Name (Pango lineage)	Spike Protein Substitutions	Name (Nextstrain[a])	First Detected	Known Attributes
B.1.1.7	Δ69/70 Δ144Y (E484K*) (S494P*) N501Y A570D D614G P681H	20I/501Y.V1	United Kingdom	•~50% increased transmission [5] •Likely increased severity based on hospitalizations and case fatality rates [6] •Minimal impact on neutralization by EUA monoclonal antibody therapeutics [7, 14] •Minimal impact on neutralization by convalescent and post-vaccination sera [8,9,10,11,12,13,19]
P.1	K417N/T E484K N501Y D614G	20J/501Y.V3	Japan/ Brazil	•Moderate impact on neutralization by EUA monoclonal antibody therapeutics [7,14] •Reduced neutralization by convalescent and post-vaccination sera [15]
B.1.351	K417N E484K N501Y D614G	20H/501.V2	South Africa	•~50% increased transmission [16] • Moderate impact on neutralization by EUA monoclonal antibody therapeutics [7,14] •Moderate reduction on neutralization by convalescent and post-vaccination sera [8,12,18,19,20]
B.1.427	L452R D614G	20C/S:452R	US-California	•~20% increased transmissibility [21] •Significant impact on neutralization by some, but not all, EUA therapeutics •Moderate reduction in neutralization using convalescent and post-vaccination sera [21]
B.1.429	S13I W152C L452R D614G	20C/S:452R	US-California	•~20% increased transmissibility [21] •Significant impact on neutralization by some, but not all, EUA therapeutics •Moderate reduction in neutralization using convalescent and post-vaccination sera [21]

National SARS-CoV-2 Variant Proportions

Rolling 12-week Period



Four weeks ending February 27, 2021

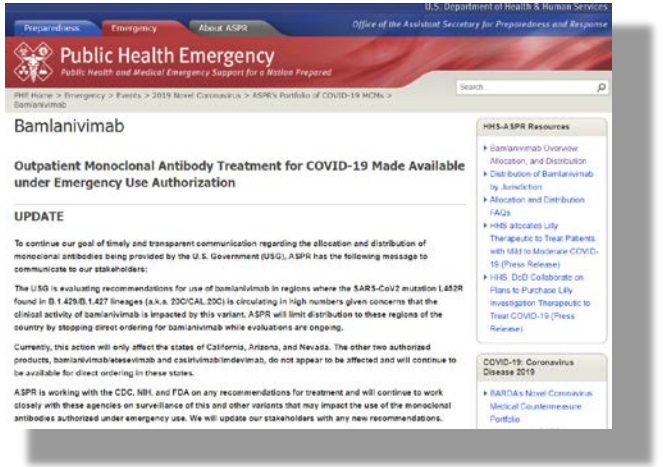
	Lineage	% Total	Type
Most common lineages	B.1.2	41.5%	
	B.1.429	9.2%	VOC
	B.1	8.9%	
	B.1.1.7	7.0%	VOC
	B.1.427	4.1%	VOC
	B.1.1.222	3.8%	
	B.1.526	2.7%	VOI
	B.1.243	2.3%	
	B.1.234	1.7%	
	B.1.311	1.0%	
Additional VOI/VOC lineages	P.2	0.7%	VOI
	B.1.351	0.3%	VOC
	B.1.525	0.2%	VOI
	P.1	0.1%	VOC
Other*	Other	16.5%	

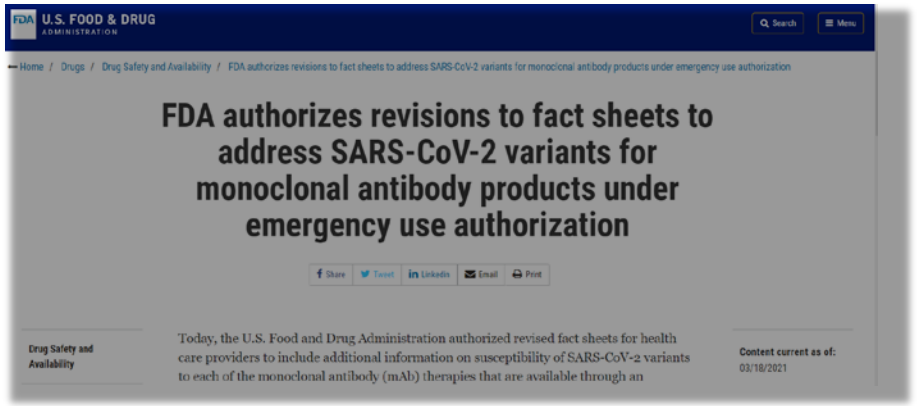
Percentages represent the proportion of viruses belonging to the indicated lineage, based on four weeks of data with collection dates ending Feb 27.
* Other represents >200 additional lineages which are each circulating at <2% of viruses.
** Most recent data (shaded) are subject to change as samples from that period are still being processed.

- Representative specimens from NS3 and CDC contracts
- >25,000 sequences total for specimens collected December 27, 2020 to February 27, 2021
- B.1.1.7, B.1.427, and B.1.429 VOCs are increasing nationally
- B.1.351 and P.1 VOCs remain well below 0.5%.

State-level SARS-CoV-2 Variant Proportions

- Expect these data will change
- Table on new Variant Proportions in the U.S. | CDC page
  - CDC sequence data: NS3 and contract laboratories
  - Four weeks ending February 13, 2021
- VOC proportion estimates shown for states meeting threshold of 300 sequences from specimens collected during timeframe
  - 19 states
  - B.1.1.7, B.1.351, P.1, B.1.427, B.1.429
- USG chose to use a threshold of 20% prevalence of L452R to guide distribution of bamlanivimab
  - This action will only affect the states of California, Arizona and Nevada at this time
- Currently, CDC is **not** requesting that B.1.427/B.1.429 variants be reported
  - If that guidance changes, CDC will notify jurisdictions and partners
- **B.1.427/B.1.429 Proportions**
- Arizona: 25.2%
- California: 52.4%
- Nevada: 41.3%

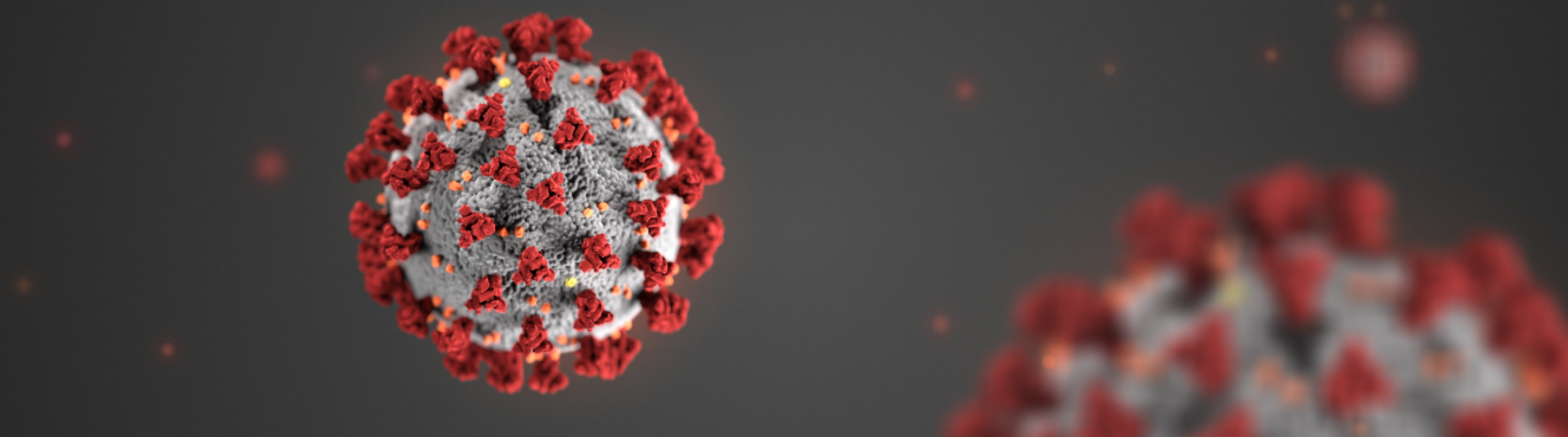




https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab/Pages/default.aspx

https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html

FDA authorizes revisions to fact sheets to address SARS-CoV-2 variants for monoclonal antibody products under emergency use authorization | FDA



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

COVID detect:

Longitudinal comparison of multimodal CoV test results with live virus shedding

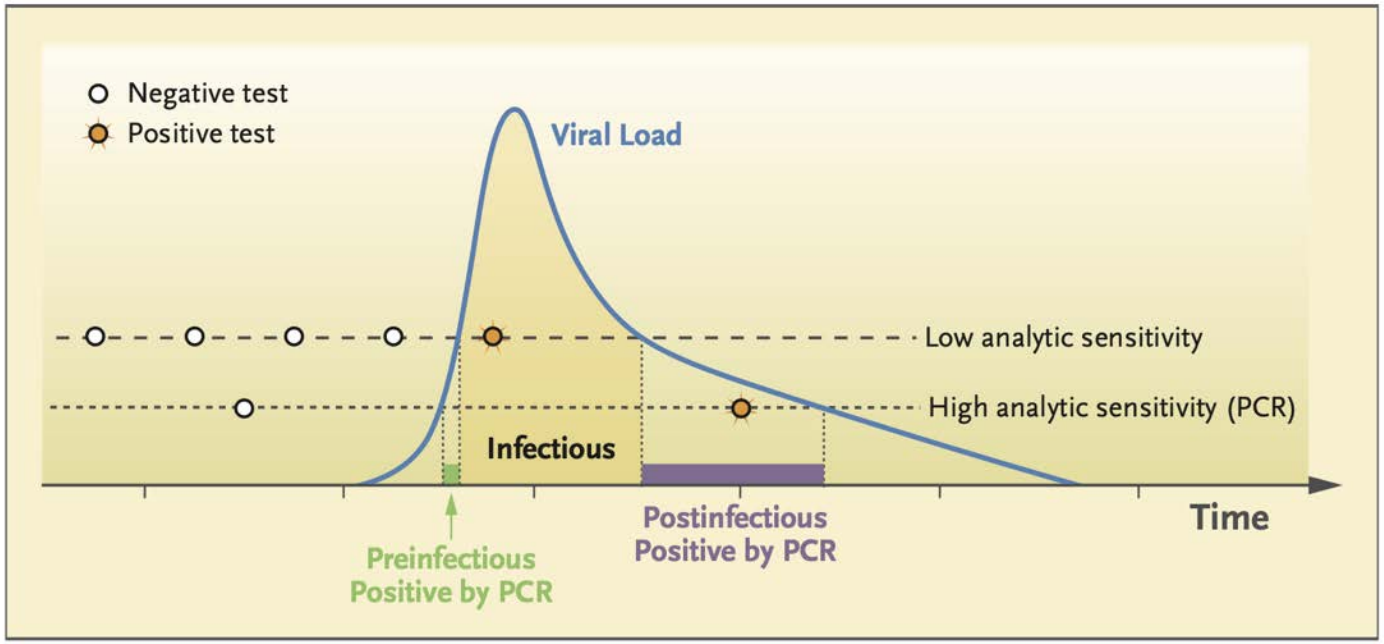
Chris Brooke
Dept. of Microbiology
Carl R. Woese Institute for Genomic Biology

Becky Smith
Dept. of Pathobiology
Carl R. Woese Institute for Genomic Biology

Primary study objectives:

(1) Quantitatively compare the performance of different diagnostic testing methods over the course of acute SARS-CoV-2 infection

(2) Generate a high-resolution description of acute infection dynamics

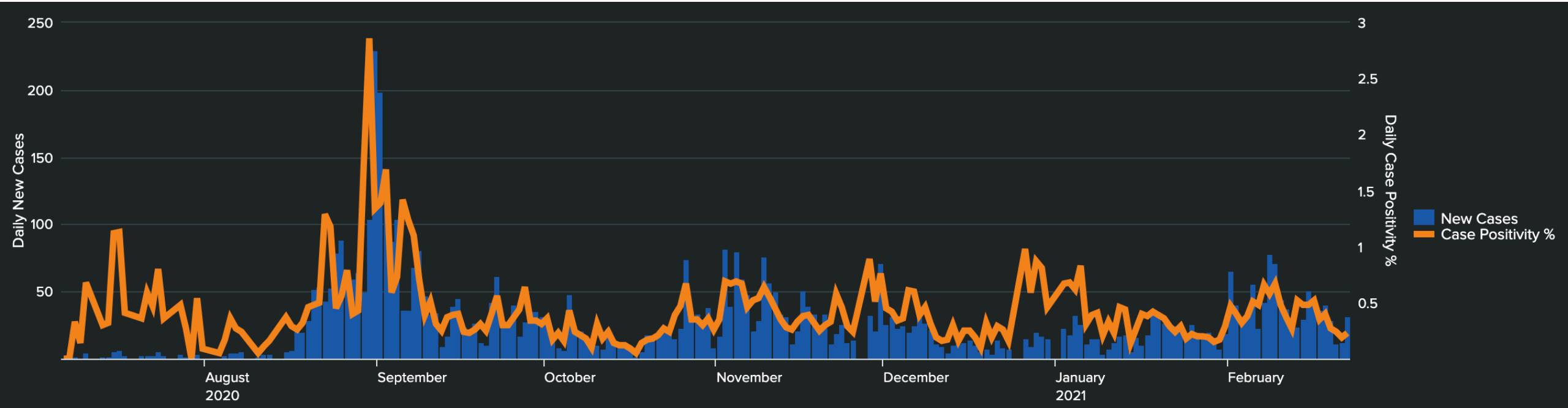


High-Frequency Testing with Low Analytic Sensitivity versus Low-Frequency Testing with High Analytic Sensitivity.

https://www.nejm.org/doi/full/10.1056/NEJMp2025631

The SHIELD CoV screening program at UIUC

All students/faculty/staff on campus are screened at least 2X weekly using our in-house saliva->qPCR assay

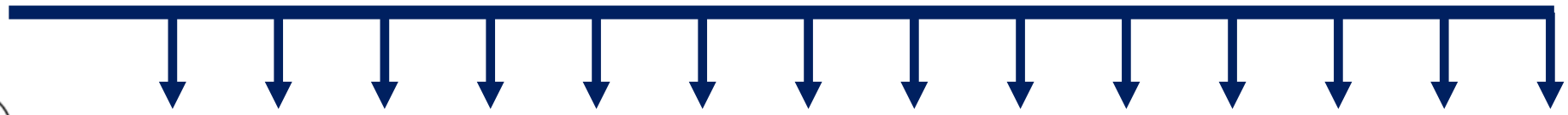


Enrollment/cohort characteristics

Study participant pool:

1) Individuals within 24 hrs of their first positive CoV test (*isolation; 116 enrolled*)

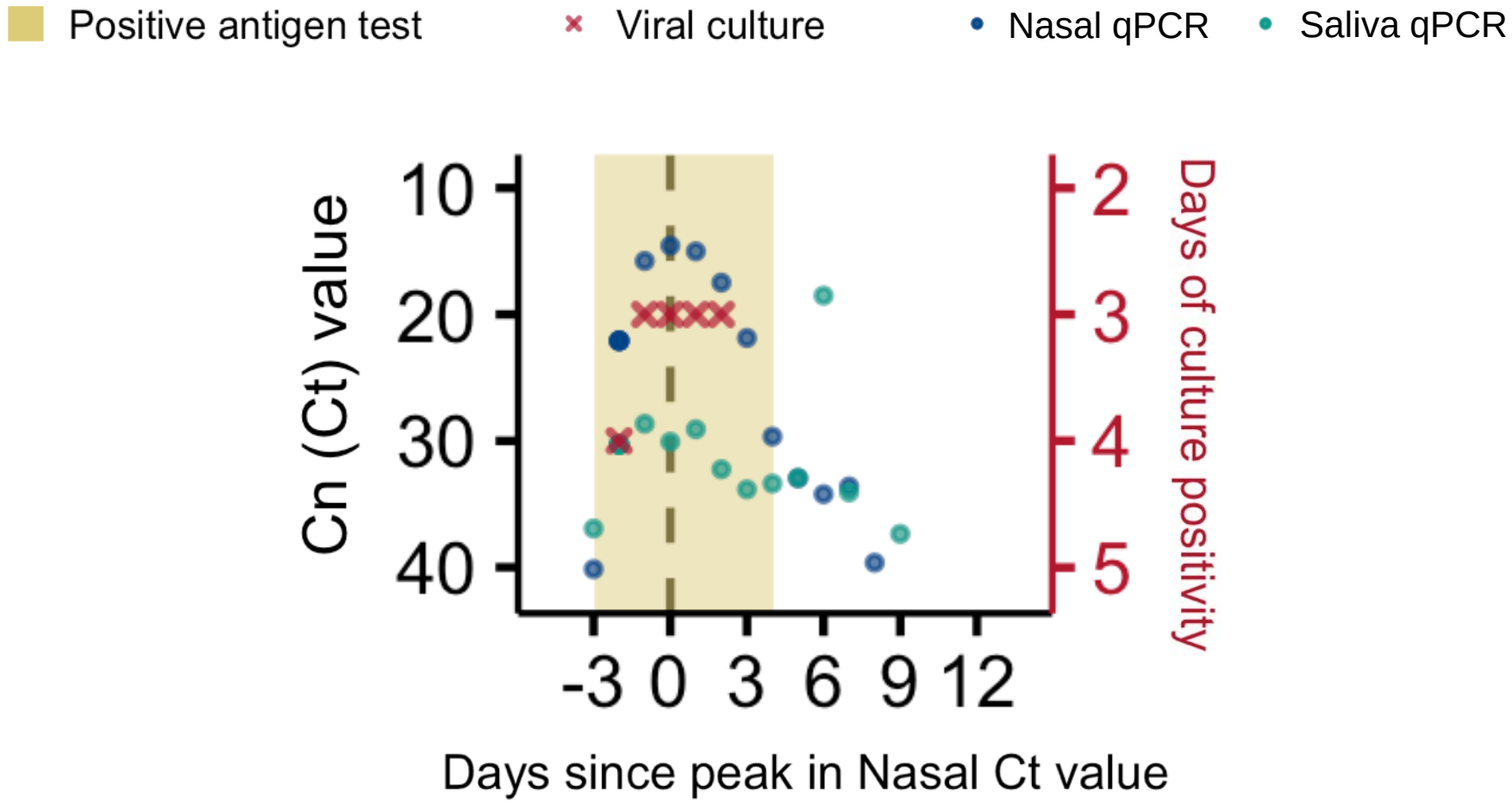
1) Individuals within 5 days of exposure to a known positive (*quarantine; 33 enrolled, 3 infected*)



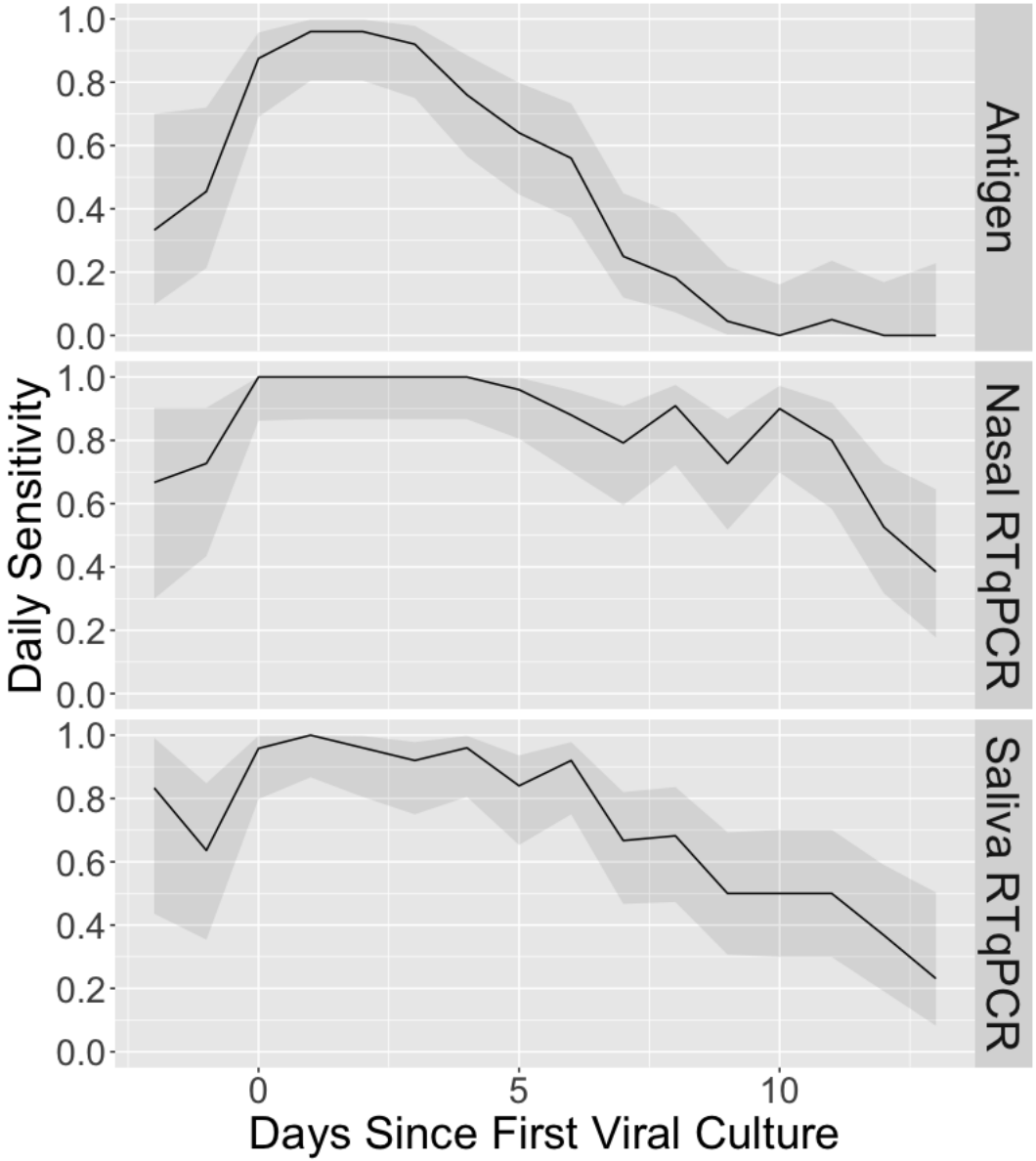
14 days

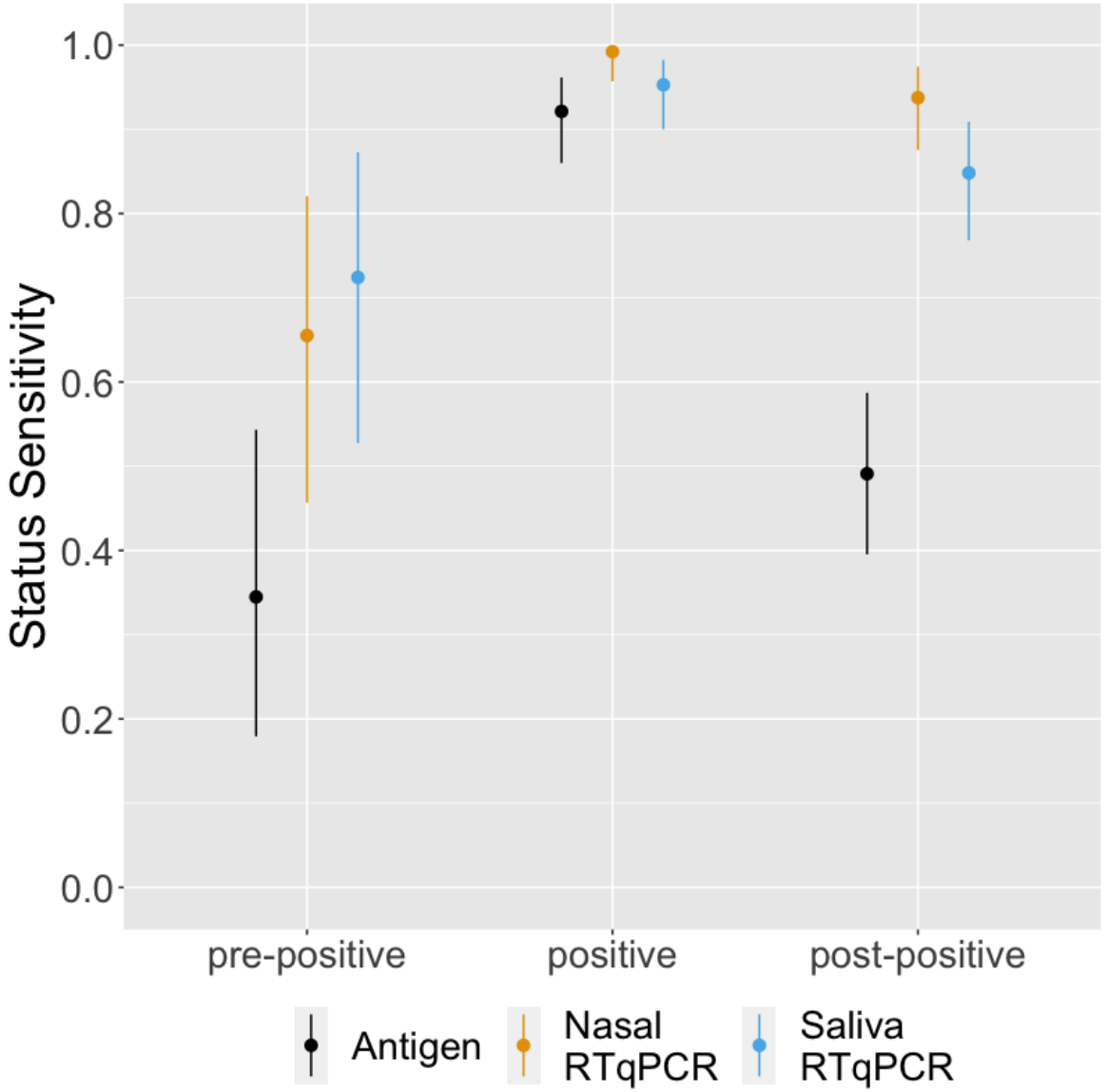
(1) Saliva RTqPCR, **(2)** nasal RTqPCR, **(3)** Quidel SARS Sofia FIA, **(4)** nasal viral infectivity, **(5)** symptom reporting

Longitudinal quantification of viral dynamics



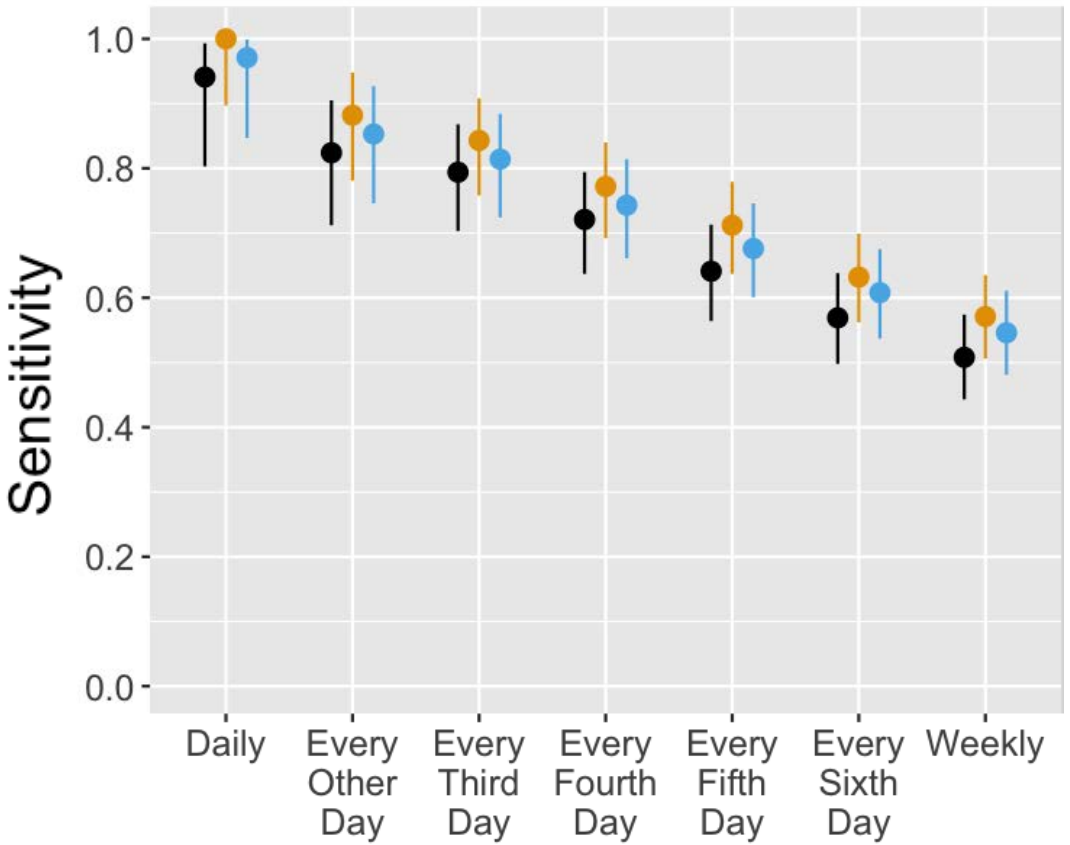
Comparison of test sensitivities



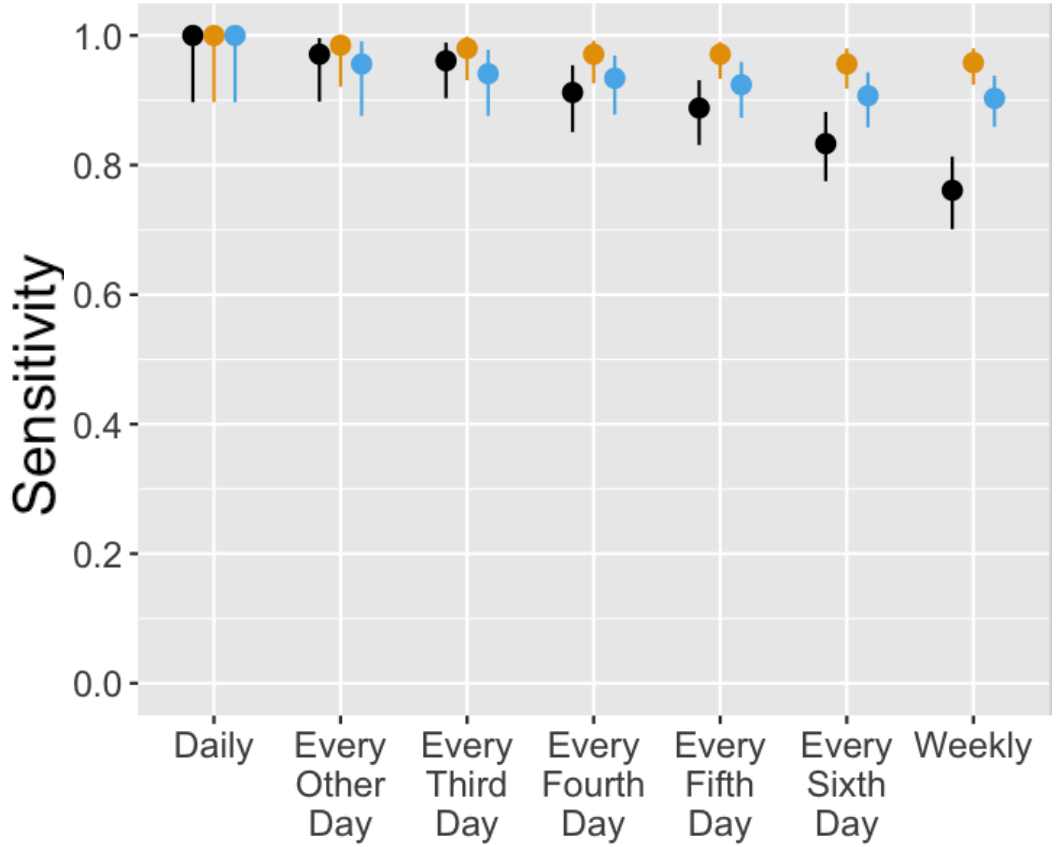


Comparison of test sensitivities

Detection before or while viral culture positive:



Detection of infection at any stage:



Conclusions

- RTqPCR is more sensitive than Quidel assay prior to and following the period of viral culture positivity
- All test modalities compared peaked in sensitivity during the period of viral culture positivity
- Screening at least twice a week by antigen or RTqPCR test will give sensitivity of ~95% or greater for detecting infection
- High frequency testing is especially important for identifying infected individuals prior to or during infectious period

Acknowledgments

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Karen Chiu
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Kevin Scardina

Gillian Snyder
Michelle Lore

COVID detect study team

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UCSF – Eureka team:
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Xochitl Butler
Noah Peyser

Quidel:
Ron Lollar

CMS Update

Monique Spruill
Centers for Medicare and Medicaid Services (CMS)

Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**

  https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health

- **FAQs Only**

  https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus

FDA Update

Tim Stenzel
U.S. Food and Drug Administration (FDA)

U.S. Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- **COVID-19 In Vitro Diagnostic EUAs**
  https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
- **COVID-19 Frequently Asked Questions**
  https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions
- **COVID-19 Updates**
  https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov
- **FDA Townhall Meetings**
  https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020
- **Independent Evaluations of COVID-19 Serological Tests**
  https://open.fda.gov/apis/device/covid19serology/

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)

- **COVID-19 Diagnostic Development**
  CDRH-EUA-Templates@fda.hhs.gov

- **Spot Shortages of Testing Supplies: 24-Hour Support Available**
  1. Call 1-888-INFO-FDA (1-888-463-6332)
  2. Then press star (*)

- **FDA MedWatch**
  https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

U.S. FOOD & DRUG ADMINISTRATION

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Thank You For Your Time!

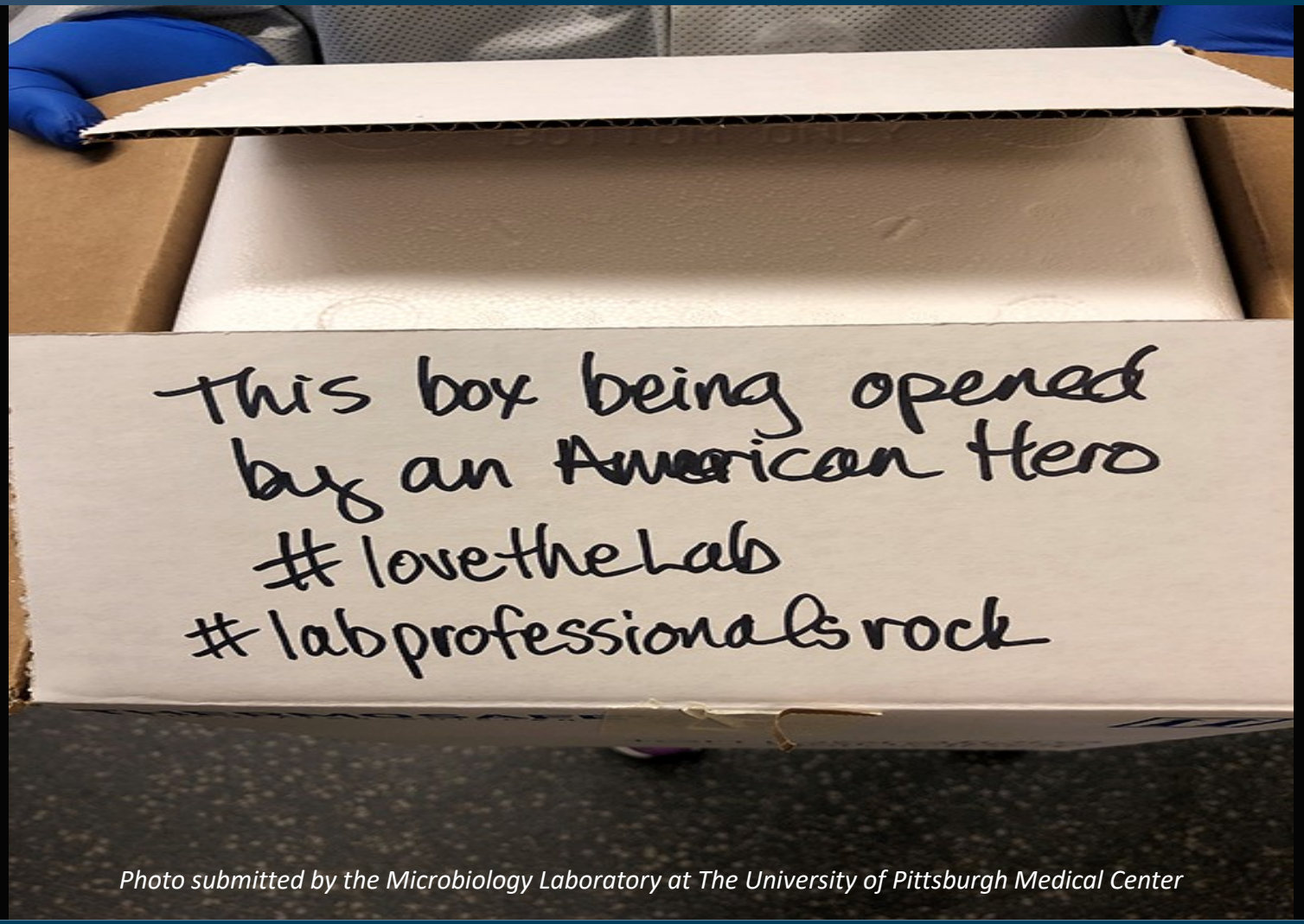

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center