Clinical Laboratory COVID-19 Response Call
Monday, May 17, 2021 at 3:00 PM EDT

• Welcome
  – Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

• Interim Guidance for Antigen Testing for SARS-CoV-2
  – Muktha Natrajan, CDC Division of Laboratory Systems (DLS)

• Biosafety Guidance Update
  – Aufra C. Araujo, CDC Division of Laboratory Systems (DLS)

• SARS-CoV-2 Variants Update
  – Steve Oberste, CDC Laboratory and Testing Task Force for the COVID-19 Response

• How the Federal Government is Addressing Laboratory Supply Issues
  – Steven Santos, HHS Testing and Diagnostics Workgroup
  – Matthew Hubbard, HHS Testing and Diagnostics Workgroup

• FDA Update
  – Tim Stenzel, U.S. Food and Drug Administration (FDA)
Find CLCR call information, transcripts, and audio recordings on the CDC Preparedness Portal

The next call will be on **Monday, June 14** 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](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider
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Interim Guidance for Antigen Testing for SARS-CoV-2

Update as of May 13, 2021


LT Muktha Natrajan, PhD, MPH
Reynolds Salerno, PhD, Director of DLS
CDC Division of Laboratory Systems (DLS)

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC).
Purpose of Guidance

Support effective clinical and public health use of antigen tests

Factors that affect Test Accuracy and Pre-test Probability

Test Strategy
- Diagnostic
- Screening / Serial
- Surveillance

Test Processing
- Storage / Handling of Components
- Timing and Batching of Specimens
- Specimen Integrity and Performance Conditions

Clinical Context
- COVID-19 Symptoms
- COVID-19 Vaccination
- Recent SARS-CoV-2 Infection

Community Factors
- COVID-19 Exposure
- Community Prevalence
- Living Setting
Summary of Recent Changes

• Updated guidance based on new published studies on antigen test performance.
• Clarification about which Nucleic Acid Amplification Tests (NAATs) should be used for confirmatory testing.
• Considerations for people who have had previous SARS-CoV-2 infections and those who have been fully vaccinated.
• Two new antigen testing algorithms, one for congregate living settings, and one for community settings.
• Updates to testing suggestions for fully vaccinated, asymptomatic people.
Congregate Settings Antigen Testing Algorithm

Asymptomatic

- Antigen Negative
  - NAAT Negative: If No Known Exposure: No Need to Quarantine
  - NAAT Positive

- Antigen Positive
  - NAAT Negative: If Close Contact or Suspected Exposure: Quarantine
  - NAAT Positive

Symptomatic

- Antigen Negative
  - NAAT Negative: Indicates SARS-CoV-2 Infection: Isolate
  - NAAT Positive

- Antigen Positive
  - NAAT Negative: Indicates SARS-CoV-2 Infection: Isolate
  - NAAT Positive
Community Settings Antigen Testing Algorithm

Asymptomatic:
- Antigen Negative
- Antigen Positive

If No Known Exposure: No Need to Quarantine

Symptomatic:
- Antigen Negative
- Antigen Positive

If Close Contact or Suspected Exposure: Quarantine

Indicates SARS-CoV-2 Infection: Isolate
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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Biosafety Guidance Update

Aufra C. Araujo, PhD
CDC Division of Laboratory Systems (DLS)
Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)

Summary of Recent Changes

Updates as of May 11, 2021

- Added information on PPE to the “General Guidance” section
- Added Biological Risk Assessment: General Considerations for Laboratories resource to the “General Guidance” section
- Added Core Infection Prevention and Control Practices for Safe Healthcare Delivery resources to the “General Guidance” section
- Added OSHA Bloodborne Pathogens Standard resource to the “General Guidance” section
CDC Update on Activities for SARS-CoV-2 Variant Surveillance

M. Steven Oberste, Ph.D.
Surveillance and Emerging Variants Team
Laboratory and Testing Task Force
CDC COVID-19 Emergency Response

Acting Deputy Director, Division of Viral Diseases
NCIRD, CDC
May 17, 2021

cdc.gov/coronavirus
## B.1.617 Lineages – Variants of Interest

<table>
<thead>
<tr>
<th>Name (Pango lineage)</th>
<th>Spike Protein Substitutions</th>
<th>Name (Nextstrain)</th>
<th>First Detected</th>
<th>Attributes</th>
</tr>
</thead>
</table>
| B.1.617              | L452R, E484Q, D614G         | 20A               | India February 2021 | • Potential reduction in neutralization by some EUA monoclonal antibody treatments  
|                      |                             |                   |                | • Slightly reduced neutralization by post-vaccination sera |
|                      |                             |                   |                | • Potential reduction in neutralization by post-vaccination sera |
|                      |                             |                   |                | • Potential reduction in neutralization by post-vaccination sera |
| B.1.617.3            | T19R, G142D, L452R, E484Q, D614G, P681R, D950N | 20A               | India October 2020 | • Potential reduction in neutralization by some EUA monoclonal antibody treatments  
|                      |                             |                   |                | • Potential reduction in neutralization by post-vaccination sera |

National Prevalence of SARS-CoV-2 Variants

U.S. 1/17/2021 – 04/24/2021


Weighted estimates

- ↑ B.1.1.7 VOC increased to 66.0%
- ↑ P.1 VOC increased to 5.0%
- ↓ B.1.351 VOC decreased to 0.9%
- ↓ B.1.427/429 VOC decreased to 3.2%
- ↓ B.1.526/526.1 VOI decreased 8.2%/3.0%
- B.1.617 VOI lineages <1.0%
- Weighted estimates 4/11/21 – 4/24/21 fall within Nowcast prediction intervals

Percent of Viral Lineages

Specimen Collection Date, 2-weeks ending

Variant of Concern - Evidence of increased transmissibility, more severe disease (hospitalizations or mortality), reduced therapeutic effectiveness, significant reduction in neutralization (convalescent or vaccinee sera), diagnostic impact, assessed to be VOC by WHO/WHO SARS-CoV-2 Virus Evolution Working Group

Variant of Interest - Studies predict increase in transmissibility or specific genetic markers may affect virus receptor binding, neutralization, or therapeutic efficacy
Regional Prevalence of SARS-CoV-2 Variants

Two weeks ending April 24, 2021

- **↑B.1.1.7 VOC >50% in all regions, as predicted by Nowcast estimates**
  - >70% in regions 4-7

- **↑P.1 VOC increased as predicted**
  - >3% in all regions except region 3
  - >7% in regions 5 and 7

- **B.1.351 VOC ≥1% in regions 4, 7-10 remained stable as predicted**

- **↓B.1.427/B.1.429 VOC decreased in regions 8-10 [10.5% - 18.0%]**

- **B.1.526/B.1.526.1 VOI remained stable as predicted**

- **B.1.617.1/B.1.617.3 VOI lineages ranged from 0%-0.3%**

- **B.1.617.2 VOI ranged from 0%-2.5%**
  - ≥1.0% regions 8 and 9
Nowcast national estimates predict:

- ↑B.1.1.7 VOC to increase to 72.4%
- ↑P.1 VOC to increase to 6.2%
- ↓B.1.351 VOC to decrease to 0.6%
- ↓B.1.427/429 VOC to decrease to 1.3%
- ↓B.1.526 VOI to decrease to 6.8%
- B.1.526.1 VOI to remain steady at 2.8%
- ↑B.1.617.2 VOI to increase to 3.3%
- B.1.617.1/B.1.617.3 VOI to remain <1%
Regional Nowcast Estimates of SARS-CoV-2 Variants

Nowcast estimates predict:

- ↑B.1.1.7 VOC will increase to >60% in regions 3-10
- ↑P.1 VOC will increase in all regions
  - >10% in region 1
- ↑B.1.351 VOC to increase in regions 3, 10
- B.1.427/429 VOC will be highest in regions 9, 10
- B.1.526/B.1.526.1 VOI will be higher in regions 1-3
- ↑B.1.617.2 VOI to increase in regions 2, 7-9
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How the Federal Government is Addressing Laboratory Supply Issues

Steven Santos
HHS Testing and Diagnostics Workgroup

Matthew Hubbard
HHS Testing and Diagnostics Workgroup
These slides were shared during the call but are not available for public distribution.
U.S. Food and Drug Administration (FDA)

- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests

- A SARS-CoV-2 Nucleocapsid Variant that Affects Antigen Test Performance
  https://www.medrxiv.org/content/10.1101/2021.05.05.21256527v1

- BioFire De Novo authorized test
  https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf
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

COVID-19 Frequently Asked Questions

COVID-19 Updates

FDA Townhall Meetings

Independent Evaluations of COVID-19 Serological Tests
https://open.fda.gov/apis/device/covid19serology/
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
Thank You For Your Time!

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