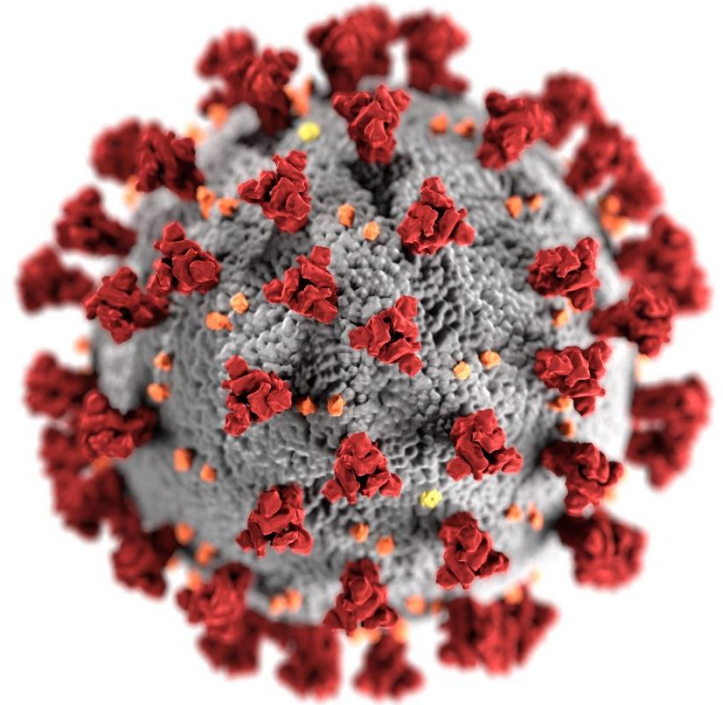


CDC COVID-19 Laboratory Response

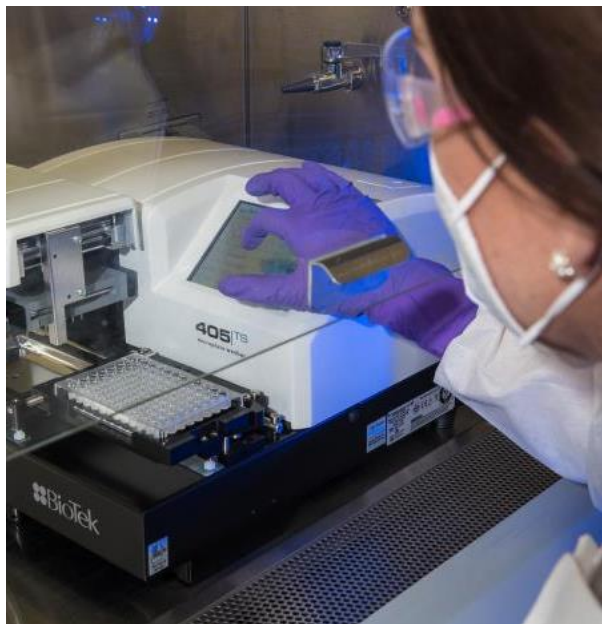
Reynolds M. Salerno, PhD
Director, Division of Laboratory Systems

The Joint Commission
2020 Laboratory Roundtable Virtual Event
October 30, 2020



cdc.gov/coronavirus

CDC COVID-19 Laboratory Response



CDC COVID-19 Laboratory and Testing Task Force

Mission

Increase scientific knowledge and laboratory testing capacity through work in CDC laboratories, support for clinical and public health laboratories, and engagement with federal partners, commercial laboratories, and professional organizations.

Functions

- Development of new laboratory tests and procedures
- Evaluation of laboratory reagents and instruments
- Development of guidance
- Support and technical assistance



Priority Areas

Laboratory Studies, Research and Development

- Assess rapid antigen test performance
- Evaluate different sample types with molecular diagnostic tests
- Validate new reagents and platforms
- Evaluate additional automated nucleic acid extraction platforms

Laboratory Testing and Support

- Support laboratories with use of CDC-developed tests and reporting
- Manage and prioritize shipments of reagents from International Reagent Resources (IRR)
- Contribute to and assess performance of reference materials

Guidance and Technical Support

- Provide technical assistance
- Develop guidance and answers to frequently asked questions (FAQs) to support PHLs and clinical laboratories
- Support outbreak investigations and transmission studies



Updates and Ongoing Activities

- Evaluation of alternative procedures, instruments, platforms and reagents for diagnostic tests
- Collaborations and partnerships to learn about rapid antigen test performance in asymptomatic people
- Development or updating of guidance and resources related to:
 - Laboratory testing
 - Biosafety
 - Point-of-care testing
- Ongoing testing, technical support, and deployments to the field



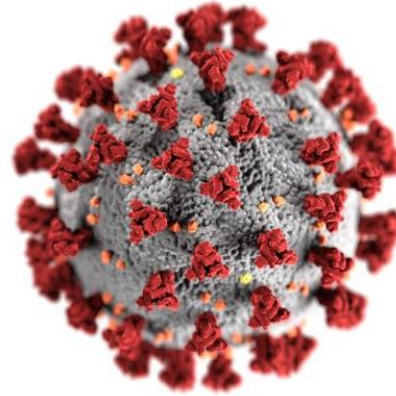
DLS Role in COVID-19 Response

Laboratory test data
collection and reporting

Public-private partnerships

Clinical laboratory
community and
outreach

Clinical laboratory
technical support



Policy support

Tri-Agency Task Force
for Emergency
Diagnostics (TTFED)

Repository services

Training and education
development support



Testing and Reporting



Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing

Purpose

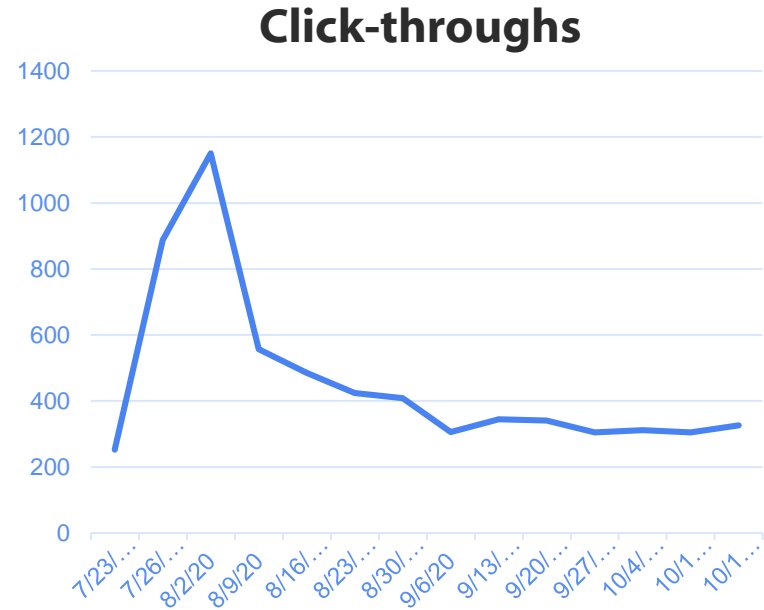
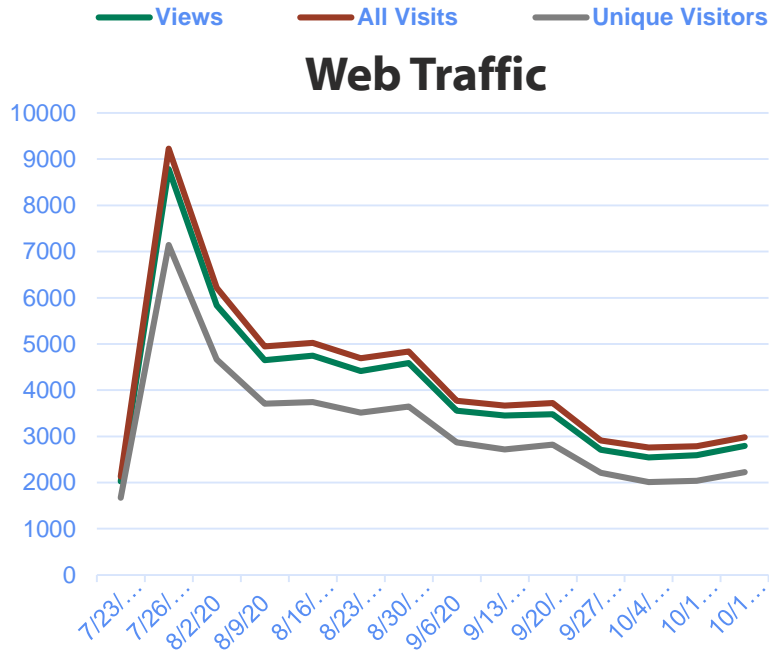
To provide guidance on the appropriate use of pooling procedures.

<https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html>



A screenshot of the CDC website. At the top, the CDC logo and name are visible. A search bar contains "COVID-19" and a search icon. Below the search bar is a navigation menu with options like "Your Health", "Community, Work & School", "Healthcare Workers & Labs", "Health Depts", "Cases & Data", and "More". A banner for "Coronavirus Disease 2019 (COVID-19)" features a row of people wearing masks and the text "WEAR A MASK. PROTECT OTHERS." Below the banner is a navigation bar with dropdown menus for "Laboratories", "Resources for Labs", "Multiplex Assay for Flu and COVID-19 & Supplies", "Diagnostic Test for COVID-19 Only & Supplies", "Calculating Percent Positivity", "Using Antigen Tests", "Using Antibody Tests", "Reporting Lab Data", "Laboratory Biosafety Guidelines", "General Laboratory Safety Practices", "Pooling Procedures", and "Specimen Collection". The main content area is titled "LABORATORIES" and "Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing". It includes a note: "Note: This document provides guidance on the appropriate use of testing and does not dictate the determination of payment decisions or insurance coverage of such testing, except as may be otherwise referenced (or prescribed) by another entity or federal or state agency." Below the note is a section titled "On This Page" with links for "Definitions of Diagnostic, Screening, and Surveillance Testing for SARS-CoV-2", "Surveillance Testing Using a Pooling Strategy", "Diagnostic or Screening Testing Using a Pooling Strategy", and "Summary Tables". At the bottom, there is a section titled "Definitions of Diagnostic, Screening, and Surveillance Testing for SARS-CoV-2" and a "What is pooling?" section with the text: "Pooling—sometimes referred to as pool testing, pooled testing or batch testing—".

Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing



Total Views: 56K Total Unique Visitors: 44K

Total Click-throughs: 6,000+

Interim Guidelines for Rapid Antigen Testing for SARS-CoV-2

Purpose

To support effective use of antigen tests for different testing situations.

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



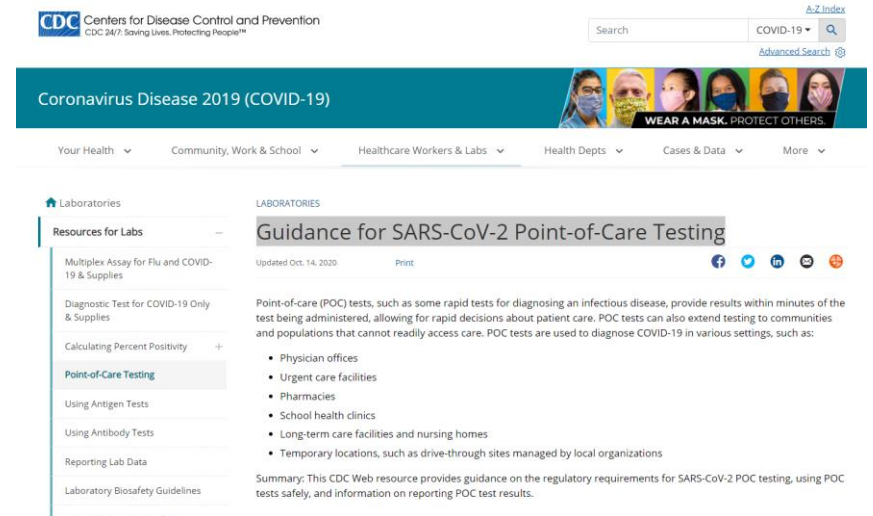
A screenshot of the CDC website. At the top, the CDC logo and name are visible. Below that is a search bar and a navigation menu. The main content area is titled "Coronavirus Disease 2019 (COVID-19)" and features a banner with images of people wearing masks and the text "WEAR A MASK. PROTECT OTHERS." Below the banner is a navigation menu with options like "Your Health", "Community, Work & School", "Healthcare Workers & Labs", "Health Depts", "Cases & Data", and "More". The "Laboratories" section is active, showing a list of resources for labs. The "Using Antigen Tests" resource is highlighted, and the main content area displays the "Interim Guidance for Rapid Antigen Testing for SARS-CoV-2" page. The page includes a note about the use of antigen tests, a list of definitions for diagnostic, screening, and surveillance testing, and a summary table. The CDC logo is also visible in the bottom left corner of the screenshot.

Guidance for SARS-CoV-2 Point-of-Care Testing

Purpose

To provide guidance on the regulatory requirements for SARS-CoV-2 point-of-care (POC) testing, using POC tests safely, and information on reporting POC test results.

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



The screenshot shows the CDC website interface. At the top, the CDC logo and name are visible, along with a search bar and a 'COVID-19' dropdown menu. Below the header is a banner for 'Coronavirus Disease 2019 (COVID-19)' with a 'WEAR A MASK. PROTECT OTHERS.' message and images of people wearing masks. A navigation menu includes 'Your Health', 'Community, Work & School', 'Healthcare Workers & Labs', 'Health Depts', 'Cases & Data', and 'More'. The main content area is titled 'Laboratories' and features a 'Resources for Labs' sidebar with links to 'Multiplex Assay for Flu and COVID-19 & Supplies', 'Diagnostic Test for COVID-19 Only & Supplies', 'Calculating Percent Positivity', 'Point-of-Care Testing' (highlighted), 'Using Antigen Tests', 'Using Antibody Tests', 'Reporting Lab Data', and 'Laboratory Biosafety Guidelines'. The main article is titled 'Guidance for SARS-CoV-2 Point-of-Care Testing', updated on Oct. 14, 2020, and includes a summary and a list of settings where POC tests are used.

Guidance for SARS-CoV-2 Point-of-Care Testing

Updated Oct. 14, 2020

Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:

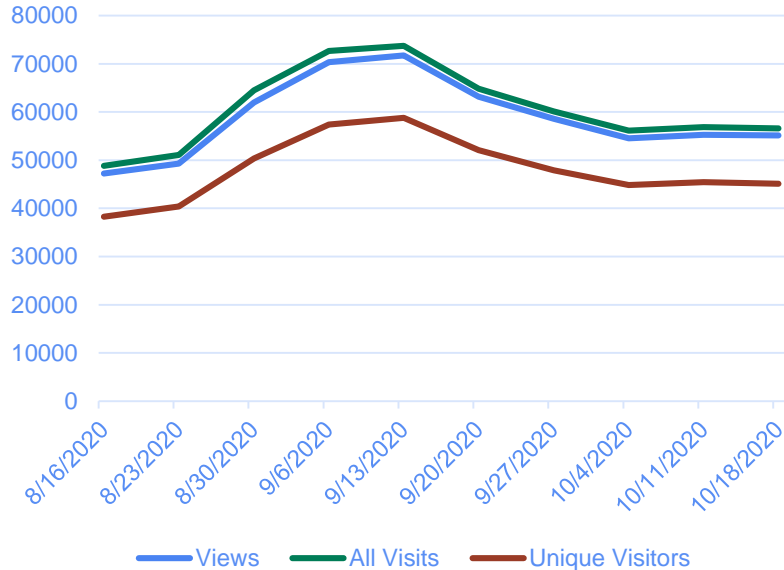
- Physician offices
- Urgent care facilities
- Pharmacies
- School health clinics
- Long-term care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations

Summary: This CDC Web resource provides guidance on the regulatory requirements for SARS-CoV-2 POC testing, using POC tests safely, and information on reporting POC test results.

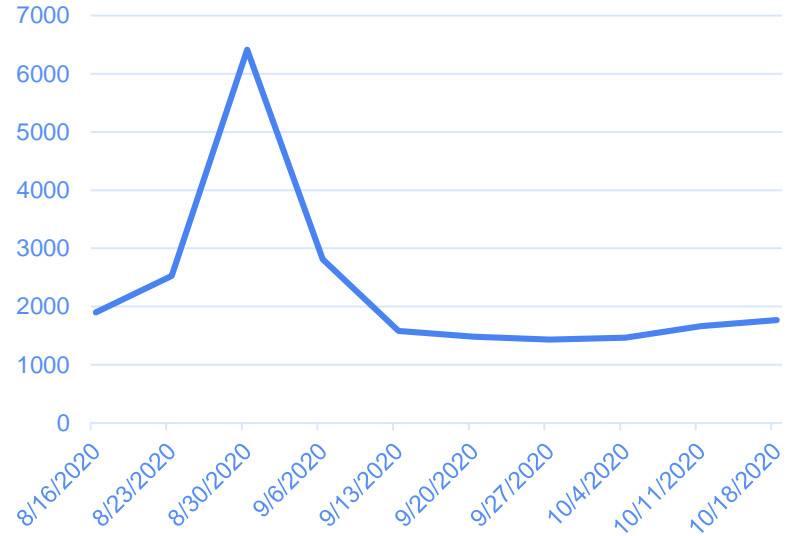


Interim Guidelines for Rapid Antigen Testing for SARS-CoV-2

Web Traffic



Click-throughs



Total Views: 587K Total Unique Visitors: 480K

Total Click-throughs: 23K

LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping Guide for SARS-CoV-2

- Provided by a Core Team of Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) members
- First posted to DLS website on 4/28/20, and updated weekly
- **365** tests mapped as of 10/5/20
- Tool has over **13,000** downloads as of 10/5/20
- <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>



Laboratory Reporting

- Provide continuous support and clarification to clinical laboratories on CARES Act, HHS, and CMS requirements for reporting laboratory data
 - LOCS messages
 - Clinical Laboratory COVID-19 calls
 - CDC laboratory reporting webpage
 - FAQs
 - Response to numerous email inquiries



Biosafety



Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19

Purpose

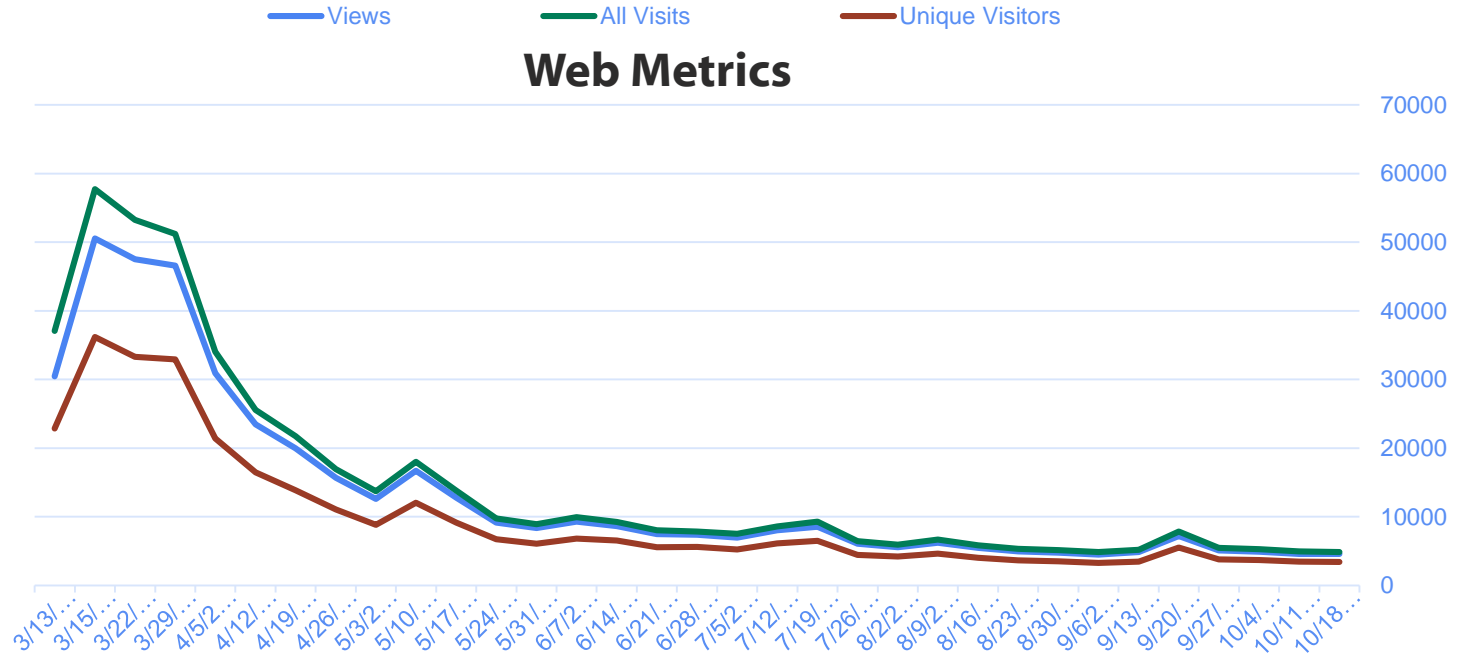
Provide support to public health and clinical laboratories through development of laboratory biosafety guidance.

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>



The screenshot shows the CDC website interface. At the top, the CDC logo and name are visible, along with a search bar and a "COVID-19" dropdown menu. Below the header, there is a navigation bar with categories like "Your Health", "Community, Work & School", "Healthcare Workers & Labs", "Health Depts", "Cases & Data", and "More". The main content area is titled "Coronavirus Disease 2019 (COVID-19)" and features a banner with the text "WEAR A MASK. PROTECT OTHERS." and images of people wearing masks. Below the banner, there is a "Laboratories" section with a list of resources for labs, including "Multiplex Assay for Flu and COVID-19 & Supplies", "Diagnostic Test for COVID-19 Only & Supplies", "Calculating Percent Positivity", "Using Antigen Tests", "Using Antibody Tests", "Reporting Lab Data", "Laboratory Biosafety Guidelines" (highlighted), "General Laboratory Safety Practices", "Pooling Procedures", "Specimen Collection", and "Publications". To the right of the list, the main article title "Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)" is displayed, along with social media sharing icons and a "Summary of Recent Changes" section. The summary lists revisions made on September 19, 2020, August 7, 2020, July 16, 2020, July 13, 2020, and June 3, 2020.

Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19

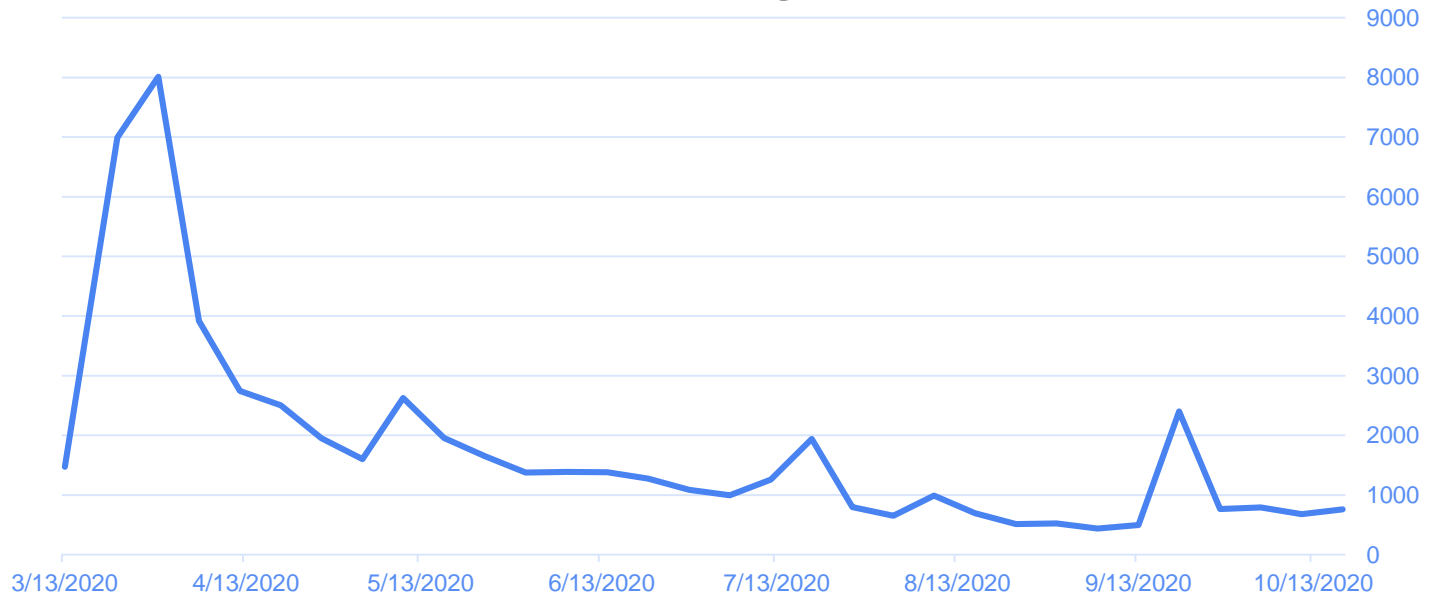


Total Views: 449K Total Unique Visitors: 324K



Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19

Click-throughs



Total Click-throughs: 64K



Laboratory Biosafety FAQs

Purpose

Provide support to public health and clinical laboratories through development of laboratory biosafety frequently asked questions (FAQs).

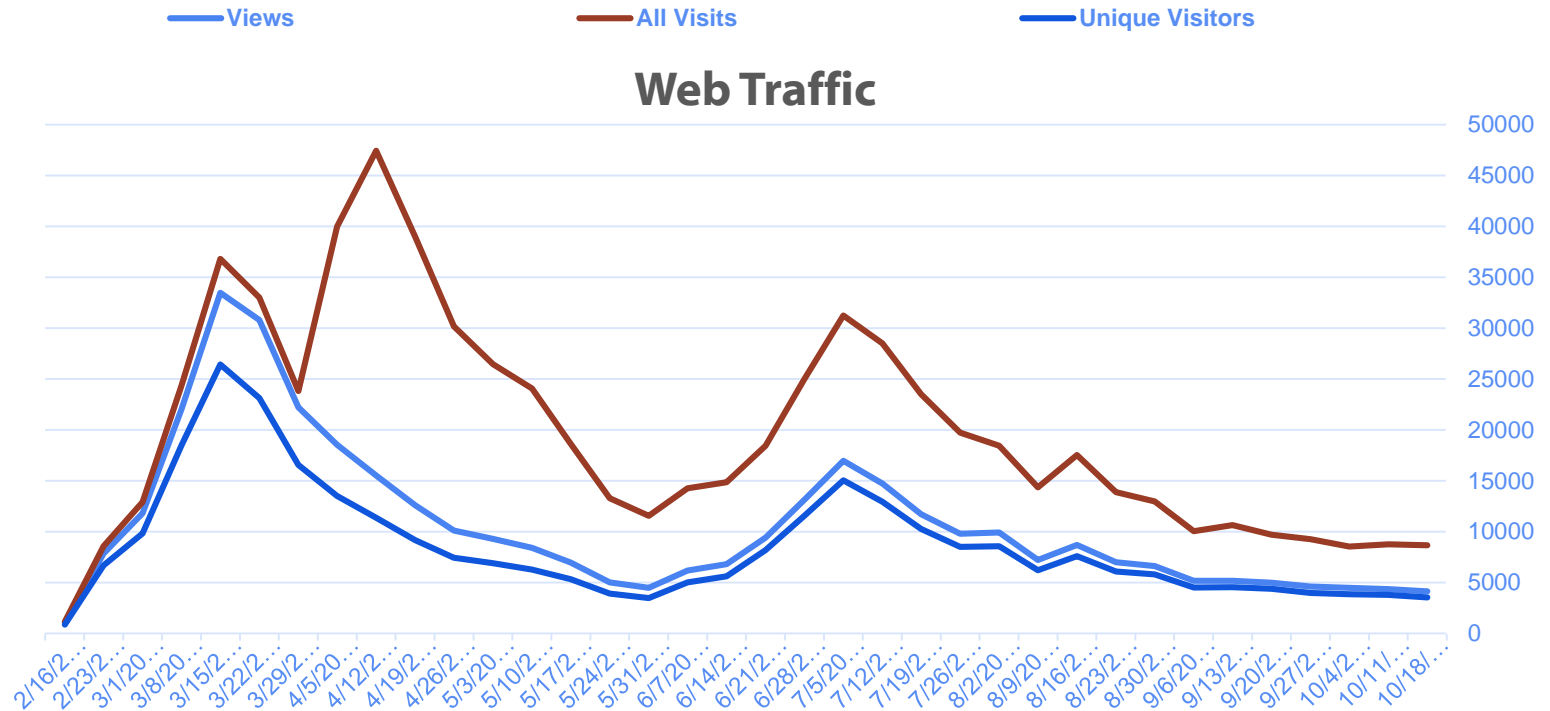
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Laboratory-Biosafety>



Laboratory Biosafety

How should the laboratory perform a risk assessment to identify and mitigate risks?	+
Are certified Class II biological safety cabinets (BSCs) required to process suspected or confirmed SARS-CoV-2 specimens? Should laboratory staff put procedures in place to minimize personnel exposure if there is no certified Class II BSC?	+
How should point-of-care testing (POCT) be conducted outside a traditional laboratory?	+
If laboratory personnel collect blood or respiratory specimens directly from suspected or confirmed COVID-19 patients, what PPE should they wear?	+
What is the recommended biosafety level for handling suspected or confirmed SARS-CoV-2 patient specimens?	+
What disinfectant should personnel use to decontaminate work surfaces?	+
How should specimens be stored?	+
How should laboratory personnel remove biohazardous waste from the laboratory or testing area for decontamination and disposal?	+
What are Standard Precautions?	+
What are infectious aerosols and droplets?	+

Laboratory Biosafety FAQs



Total Views: 381K Total Unique Visitors: 309K



Partnership, Communication, and Outreach



Partnerships

- Chairing weekly calls with Tri-Agency Task Force for Emergency Diagnostics
- Conducting calls with the American Clinical Laboratory Association (ACLA) and large commercial laboratories
- Participating in calls with the Association of Public Health Laboratories (APHL) and CDC Laboratory and Testing Task Force, and public health laboratories



Clinical Laboratory Partners Forum



Laboratory Outreach Communication System (LOCS)



<https://www.cdc.gov/csels/dls/locs>

To opt in, email LOCS@cdc.gov.

Clinical Laboratory COVID-19 Response Calls

Purpose

Biweekly call with partners, public health, and clinical laboratories to discuss the nation's laboratory response to COVID-19



21 total calls



~1,300 participants/week

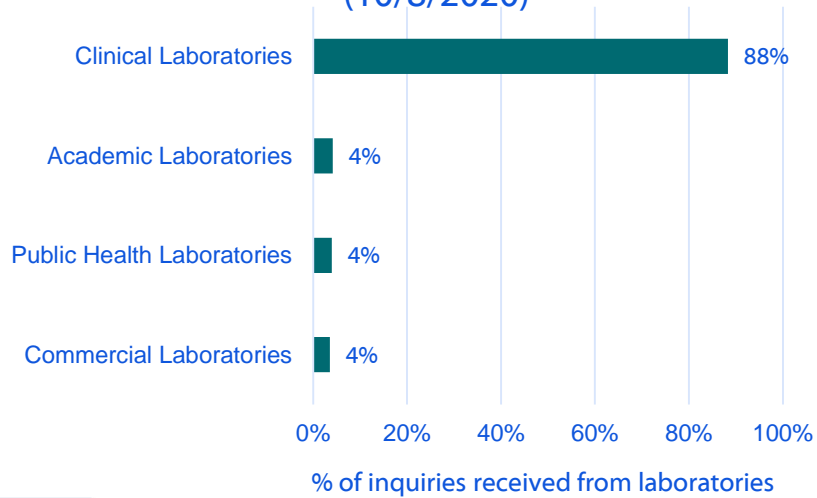


+1,000 total questions

COVID-19 Inquiries Received by DLS

- **+800** inquiries since February

Inquiries by laboratory type, to date
(10/8/2020)

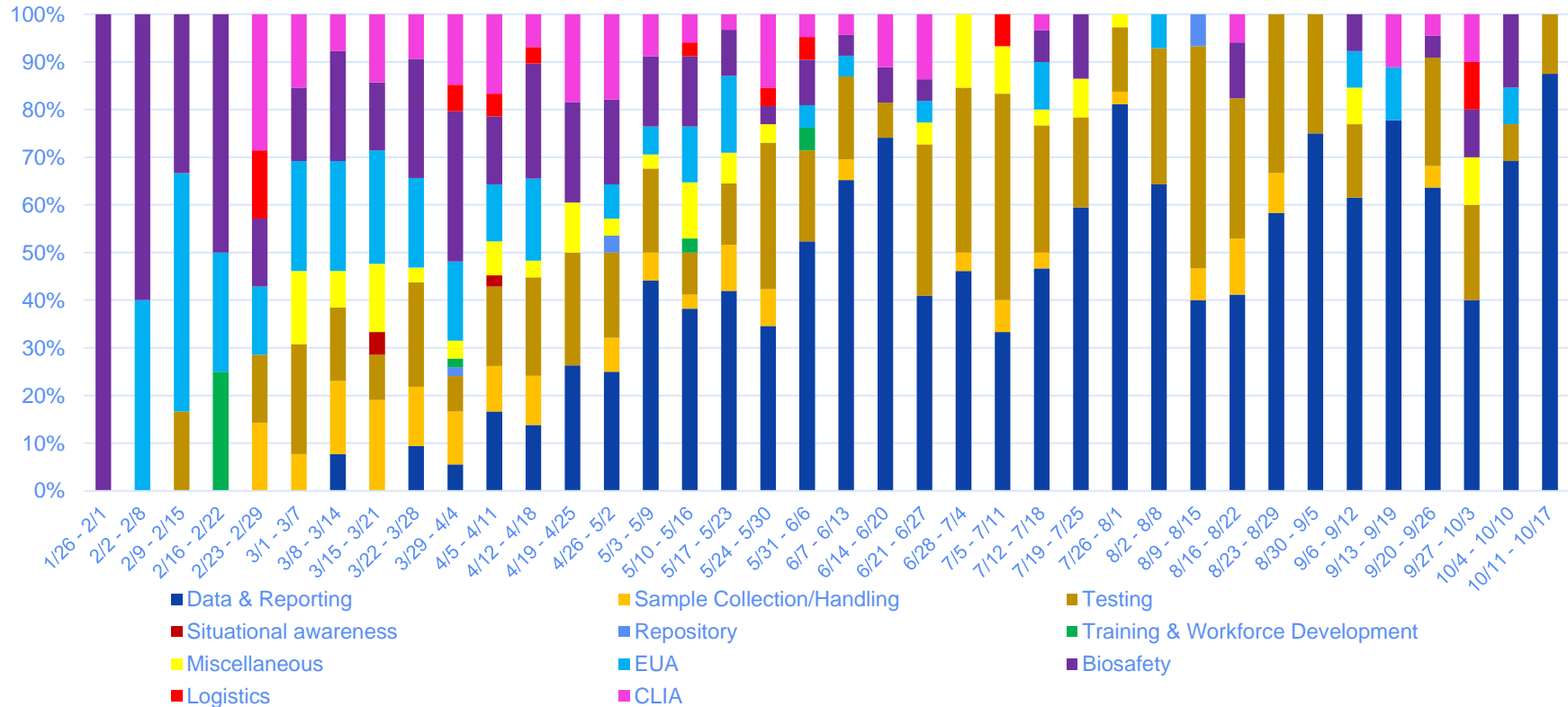


Inquiries by topic area, to date
(10/8/2020)



COVID-19 Inquiries Received by DLS

Inquiry topic areas, to date (10/17/2020)



DLS COVID-19 Web Page



www.cdc.gov/csels/dls/preparedlabs

Prepared Laboratories



Initiatives and Partnerships

Find out about initiatives and partnerships to support laboratories in a response.

Outbreak & Response

Learn how CDC supports laboratories responding to disease outbreaks and pandemics such as COVID-19.

Tools & Resources

Get products, tools, and resources to prepare laboratory staff and systems.



Policy



Legislative Engagement

- Testimony preparation
- Responses to Congressional inquiries
- Legislative technical assistance



Information Sharing and Accountability



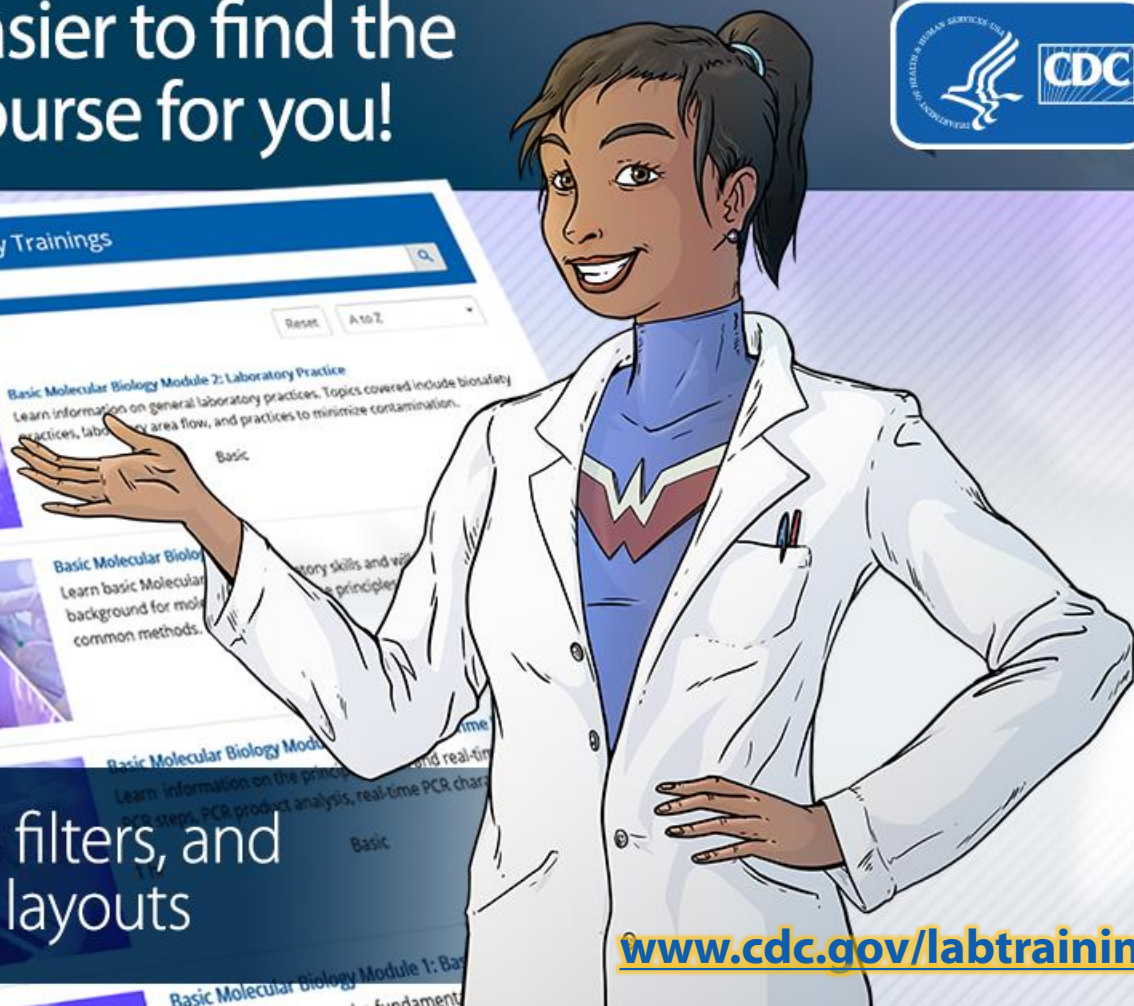
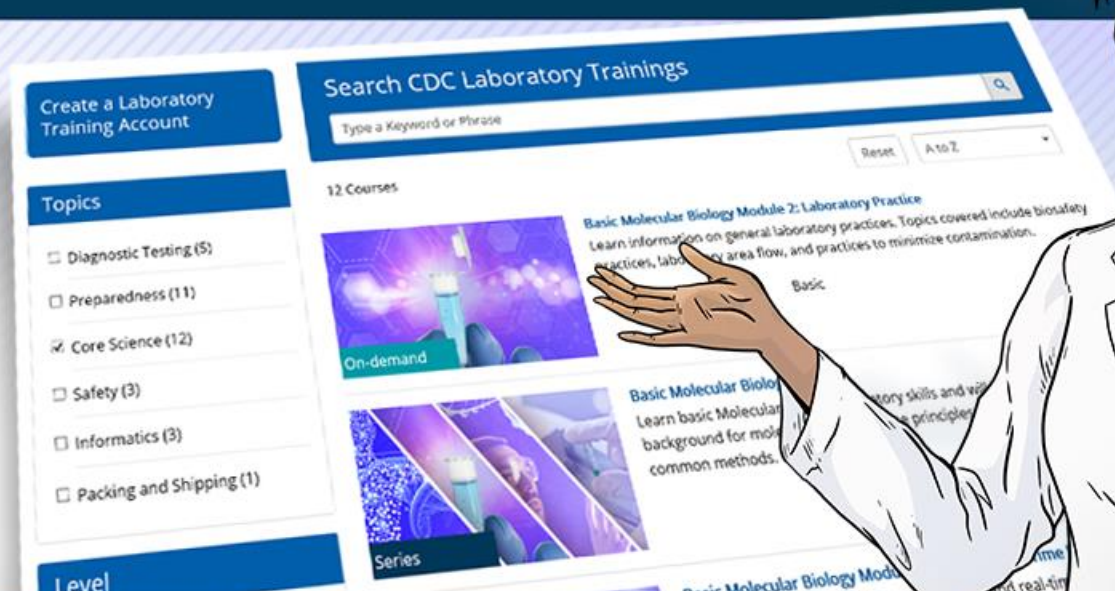
CDC Laboratory Training Update

Senia Wilkins, MPH

Branch Chief, Training Workforce and Development Branch, DLS



CDC just made it easier to find the right lab training course for you!



New search tool, active filters, and improved course page layouts

www.cdc.gov/labtraining

Now Live: Packing and Shipping Dangerous Goods



PACKING AND SHIPPING DANGEROUS GOODS:

What the Laboratory Staff Must Know





Fundamentals of Personal Protective Equipment



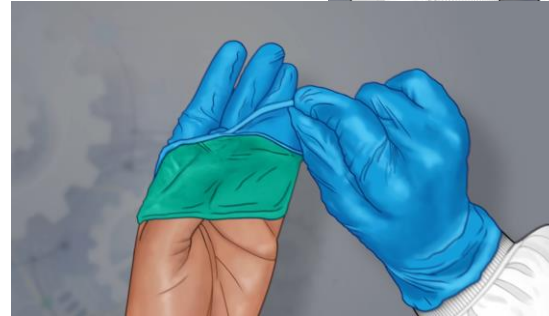
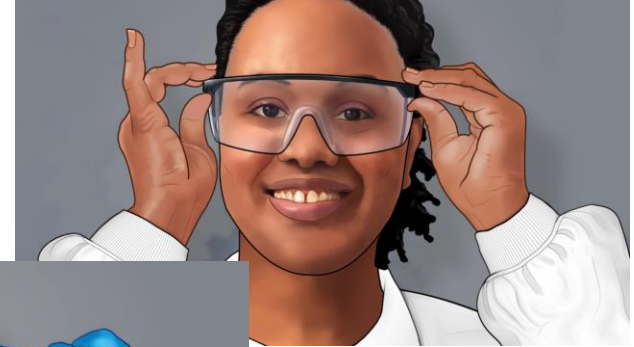


Fundamentals of Working Safely in a Biological Safety Cabinet



COVID-19 Relevant Job Aids

- Job aids posted on DLS Laboratory Training website
 - Brief videos
 - PPE
 - Flu SC2 Multiplex Assay
 - PDF and Word versions that laboratories can tailor



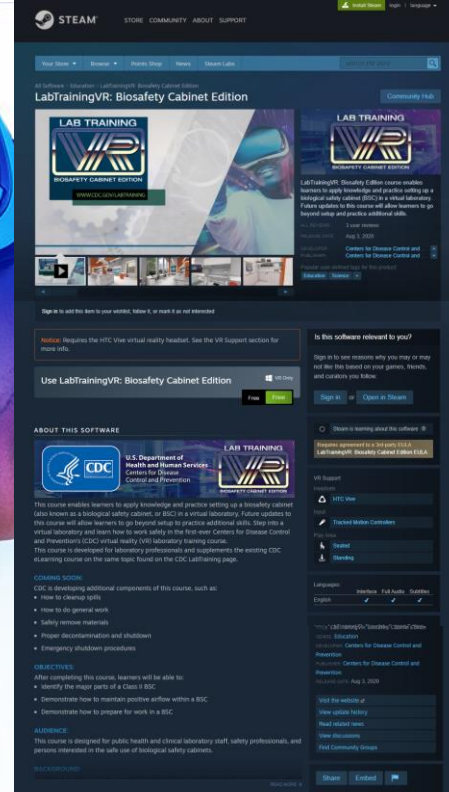
Available Now: Virtual Reality Laboratory Training



Available on
CDC TRAIN
and
STEAM[®]



cdc.gov/labtraining



CDC VR Laboratory Training Website



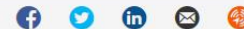
[A-Z Index](#)



[Advanced Search](#)

CDC Laboratory Training

CDC > CDC Laboratory Training



↑ CDC Laboratory Training

Virtual Reality Laboratory Training

Virtual Reality Laboratory Training Partner Toolkit

External Training Links

FAQs

Continuing Education Units (CEU)

About Us

Contact Us

Virtual Reality Laboratory Training

Public health emergencies demand the availability of diverse and effective distance-based education and training options for public health and clinical laboratory professionals. To keep pace with the evolving training needs, DLS has blended innovative technology and instructional design principles by adding Virtual Reality, or VR, to its laboratory training and workforce development toolbox.

VR offers laboratory professionals the opportunity to apply, assess, and improve their skills in a safe and controlled learning environment. In other words, VR simulations allow learners to make costly mistakes while learning new skills with no real-world consequences.

In 2019, DLS launched a three-year pilot project, in partnership with the Center



[View Transcript](#) [Low Resolution Video](#)

NOW AVAILABLE

www.cdc.gov/labtraining/VR.html

VR@cdc.gov

COMING SOON



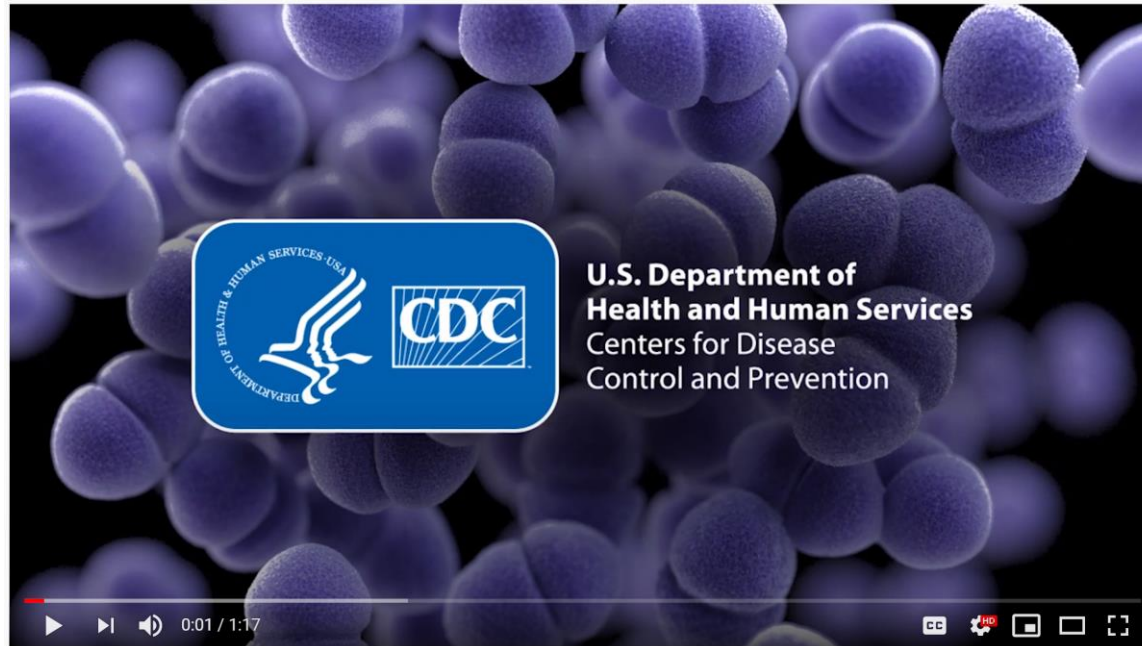
NEW SCENARIOS & OBJECTIVES



EMERGENCY PROCEDURES



VIDEO DEMO (01:06)



https://www.youtube.com/watch?v=Kmq_cBn_7Yk



COMING SOON

LAB TRAINING



PPE EDITION

LAB TRAINING



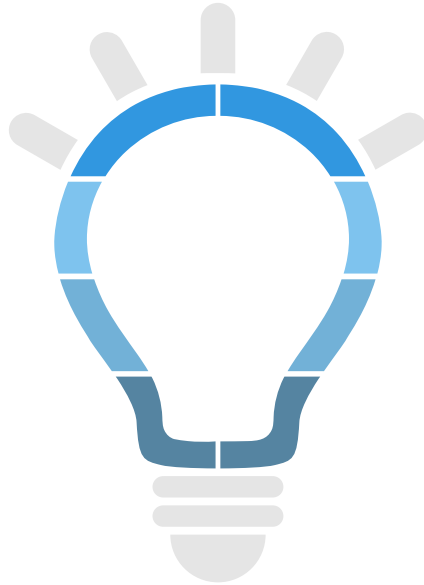
MULTIPLAYER LAB

OneLab: A Unified Response to Training Needs

- A new laboratory training network to strengthen the US laboratory systems' ability to rapidly and effectively respond to public health emergencies through:
 - Education
 - Training
 - Outreach
- Coming soon!

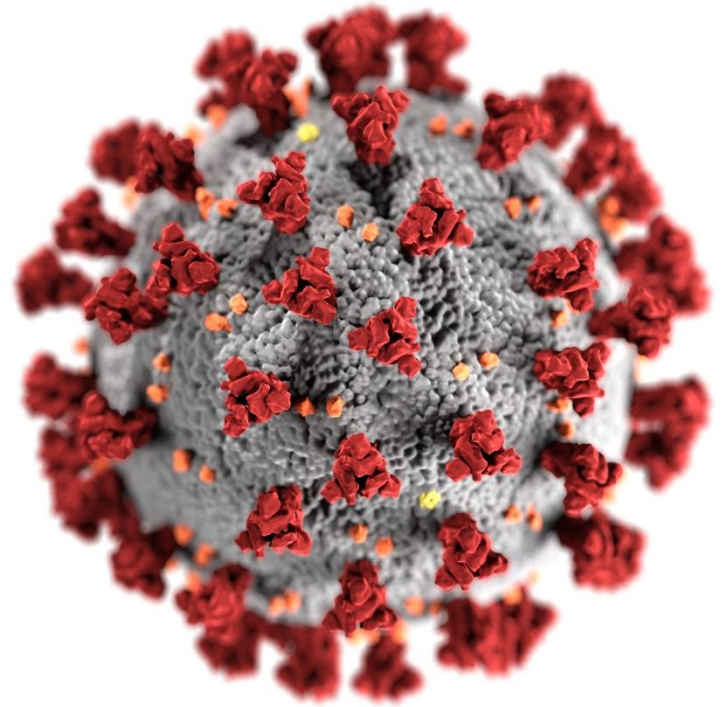


SHARE YOUR TRAINING NEEDS



E-mail LabTrainingNeeds@cdc.gov





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.

