CDC & APHL Cooperative Agreement OE20-2001: Enhancing Public Health Laboratory Capabilities and Increasing Capacity

2.5 Year Performance Summary Report

Reporting Period: July 2020 – December 2022

ABOUT THE RECIPIENT: Association of Public Health Laboratories (APHL)
APHL works to strengthen laboratory systems serving the public's health in the United States and globally. Its members, known as "public health laboratories," monitor, detect, and respond to health threats. With over 20 years' experience in more than 30 countries, APHL is recognized internationally as a leader in public health laboratory science and practice.

OE20-2001: ENHANCING PUBLIC HEALTH LABORATORY CAPABILITIES AND INCREASING CAPACITY

Building upon previous and currently funded Cooperative Agreements (CoAgs) between CDC and the Association of Public Health Laboratories (APHL), OE20-2001 aims to improve public health in the United States and globally by enhancing the effectiveness and functionality of public health laboratories (PHLs), individually and as components of a national system. This CoAg supports four key strategies and activities that will enhance the capabilities and increase the capacities of PHLs in nine focus areas (FA).

FOCUS AREAS

A. Foundational Leadership and Support
B. Environmental Health
C. Foodborne, Waterborne, and Environmentally Transmitted Diseases
D. Infectious Diseases
E. Informatics
F. Newborn Screening and Genetics
G. Preparedness and Response
H. Quality and Safety Systems
I. Workforce Development

STRATEGIES

Strategy 1
Science, Management, and Operations

Strategy 2
Policy, Partnership, and Communications

Strategy 3
Training and Capacity Building

Strategy 4
Laboratory Quality, Safety, and Informatics

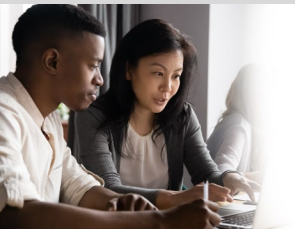
SELECTED STRATEGIES AND ACTIVITIES

SCIENCE, MANAGEMENT, AND OPERATIONS

- Provide leadership and management approaches to ensure organizational efficiency and operational improvement.
- Provide appropriate monitoring, evaluation, and scientific services.

APHL CAREER PATHWAYS in Public Health Laboratory Science
An APHL-CDC Initiative

POLICY, PARTNERSHIP, AND COMMUNICATIONS



- Develop policy and issues analyses to promote public health laboratory interests.
- Facilitate information exchange and dissemination between laboratory professionals and other partners in public health, healthcare and beyond.
- Collect and analyze information, create content, and disseminate products to inform partners about the role of public health laboratories and the tools and resources available to them.

TRAINING AND CAPACITY BUILDING

APHL ACADEMIC PARTNERSHIP PROGRAM

- Identify training and workforce development needs among laboratory professionals in diverse settings.
- Develop curriculum frameworks and training and workforce development resources for laboratory professionals in diverse settings.
- Design and implement programs to strengthen the public health laboratory workforce pipeline.

LABORATORY QUALITY, SAFETY, AND INFORMATICS

APHL Informatics Messaging Services
AIMS

- Develop and implement solutions and standards to improve data exchange and interoperability.
- Improve the practice of laboratory quality and safety in public health laboratories.
- Employ emerging methodologies and process improvements in public health laboratories.
- Provide technical assistance to public health laboratories and other partners.
- Identify and address gaps in laboratory preparedness and response to public health threats.

Cross-Cutting Performance Summary

REPORTING PERIOD: JULY 2020 – DECEMBER 2022

HIGHLIGHTS: CROSS-CUTTING PERFORMANCE MEASURES

POLICY, PARTNERSHIP, AND COMMUNICATIONS

35

Number of legislative bills related to PHL priorities that were communicated to members via factsheets.

4,003

Number of individuals who participated in key APHL collaborations.

90

Number of evidence-based tools and resources developed.

73%

Proportion of completed responses received (N=3,396) for formal needs assessments and resource development.

TRAINING AND CAPACITY BUILDING

28,322

Number of individuals who participated in APHL training and workforce development opportunities.

794

Number of trainings and workforce development opportunities delivered to address public health laboratory workforce needs.

LABORATORY QUALITY, SAFETY AND INFORMATICS

86%

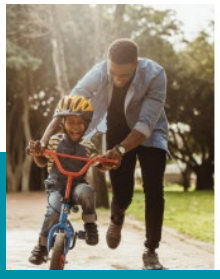
Proportion of 43 new/updated resources developed to facilitate implementation of quality and safety systems and standards to address identified challenges and gaps.

359

Number of formal technical assistance requests fulfilled through subject matter expert (SME) services.

1,654

Number of standardized guidelines for data exchange/transmissions developed/updated that addressed priority informatics needs.



GUIDANCE FOR LABORATORY BIOMONITORING PROGRAMS

Developing Biomonitoring Capabilities

1,256

Number of views of the Guidance for Laboratory Biomonitoring Programs webpage with new or updated resources (guidance documents, shared service models, etc.).

Note: Science, Management, and Operations (Strategy 1) does not have cross-cutting performance measure data to report on.

Strategy 1: Science, Management, and Operations

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

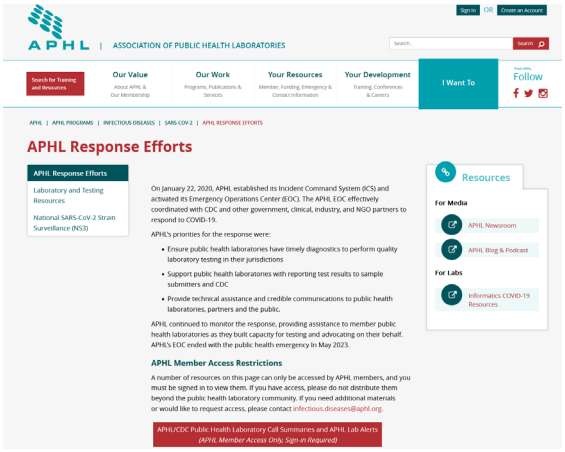
- **Monitoring and Evaluation (M&E) System:** In Year 1 of the CoAg, APHL partnered with the CDC's Division of Laboratory Systems (DLS) to design a new centralized M&E system for the OE20-2001 CoAg for all nine focus areas. In Year 2 of the CoAg, personnel from CDC and APHL prioritized performance measures towards lower reporting effort while sustaining high impact. Original measures were reduced by 65% to 1,152 annually, with 216 narrative (19%), 229 program-specific (20%) and 707 cross-cutting (61%). With 3,010 data points reported across the CoAg by December 2022, six-month and one-year evaluation briefs were produced, co-branded and published to CDC's website (FA A).
- **Data Modernization Initiative:** APHL continued to lead the support of the CDC Data Modernization Initiative, resulting in $1.275 billion in federal funding to improve data management efforts both for CDC and for external partners, including PHLs (FA A).
- **Critical Gaps in Laboratory Capacity and Capabilities:** Three feedback sessions were conducted with over 70 Public Health participants to explore critical laboratory gaps. 22 priority laboratory gaps were identified and the results informed CDC and APHL priorities and activities. The sessions guided the development of the “Exploring critical gaps and solution strategies in laboratory capacity and capabilities for public health response workshop” report (FA G).

Strategy 2: Policy, Partnerships, and Communications

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

- **Data Science**: APHL managed 45 needs assessment surveys to support all FAs across the CoAg and oversaw ongoing surveys to support PHLs for reagent and supply allocation, as well as training needs assessments, in response to the COVID-19 pandemic. APHL also responded to 68 data requests and fulfilled 84%. The remaining 16% were not completed because they did not meet APHL's Data Sharing Policy or data were unavailable for dissemination (FA A).
- **Scientific Products:** With guidance from 13 standing committees and their associated subcommittees, taskforces and workgroups, APHL produced 126 scientific reports, tools and resources, and created a new webpage to showcase peer-reviewed publications (FA A).
- **Knowledge Management:** APHL supported projects undertaken by the Knowledge Management Committee to collect and centralize 17 committee toolkits on a new webpage and redesign the Member Resource Center in auditing 600+ documents for relevance and adding 64 new documents. Resources and toolkits have received a total of 4,783 unique page views (FA A).
- **Social Media:** APHL expanded its social media presence, with 33,766 followers on Facebook, Twitter/X, LinkedIn and Instagram (FA A).
- **Resources:** APHL published 104 just-in-time resources, including Lab Alerts and eUpdate newsletters, where CDC resources, funding announcements, and messages were featured 200 times (FA A).

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

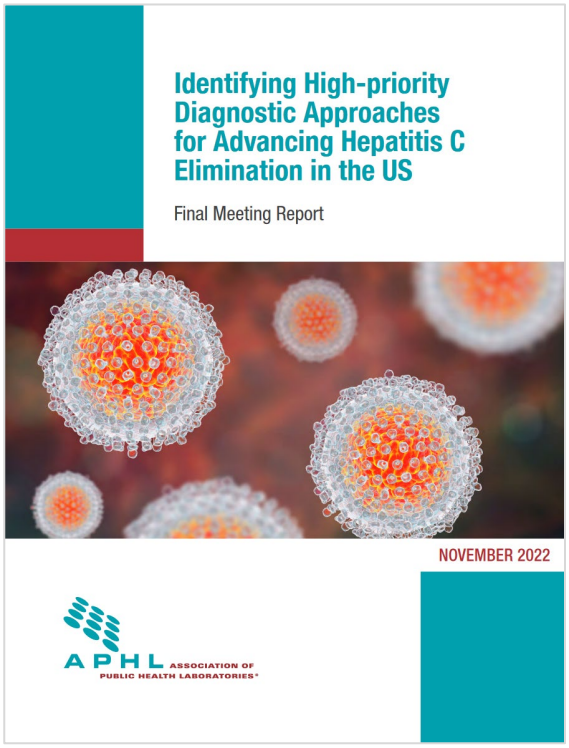


- **PHL Workforce Topics:** In support of workforce recruitment and retention efforts, APHL published a new webpage featuring multiple reports on critical workforce topics and a PHL Salary Comparison dashboard. Since its launch in the summer of 2022, the reports have received 1,092 page views and 523 unique visitors (FA A).
- **Wastewater Surveillance:** In October 2020, the National Wastewater Surveillance System (NWSS) Laboratory Community of Practice was created to connect laboratories testing community wastewater for SARS-CoV-2 and other infectious disease targets. As of December 2022, the community numbered 309 members. A publication, webinar, two conference sessions, and four articles were also created on the progress of NWSS (FA C).
- **Food Safety Program:** APHL developed a specimen collection and testing protocol for the Outbreaks of Undetermined Etiology Guidelines and collaborated with CDC to incorporate them into the System for Enteric Disease Response, Investigation, and Coordination platform (FA C).
- **COVID-19 Response:** APHL provided consistent and prompt technical assistance throughout the COVID-19 response. APHL also maintained up-to-date guidance for PHLs on processes for submission of specimens to the National SARS-CoV-2 Surveillance System (NS3) (FA D).
- **Office of Advanced Molecular Detection (OAMD):** APHL and the OAMD established five Bioinformatics communities-of-practice focused on informing the development of a national bioinformatics platform. During 21 meetings held August-December 2022, communities saw active participation with 857 attendees representing 18 states and one territory (FA D).
- **Newborn Screening (NBS) Condition Counting:** Given a lack of uniformity in how state's classify conditions on NBS testing panels, APHL's NBS Condition Counting Workgroup developed recommendations for a standard NBS condition counting convention for state panels. This framework was presented at the 2022 NBS Symposium. The workgroup is obtaining input from the Advisory Committee on Heritable Disorders in Newborns and Children (FA F).
- **Surge Testing Capacity:** During the COVID-19 pandemic, APHL supported over 200 alerts to laboratories and partners, assisted with communications on COVID-19 testing, and engaged with diverse partners to renew a CDC-managed memorandum of understanding for diagnostic surge testing capacity for public health emergencies (FA G).
- **Engagements:** APHL convened the first Laboratory Response Network for Biological Threats (LRN-B) Advanced Reference Laboratory Technical Meeting in November 2021 with over 125 attendees from LRN-B laboratories, APHL, CDC, the Department of Defense and the Federal Bureau of Investigation. The Threat Agnostic Sentinel Surveillance Pilot was also implemented to build pathogen-agnostic metagenomics workflows to support early warning and identification of public health threats and enable public health partners to implement workflows for targeted surveillance, outbreak investigation, and clinical diagnosis (FA G).

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

- **National Biomonitoring Network (NBN):** The NBN met virtually in 2022, offering a one-day National Health and Nutrition Examination Survey operational workshop attended by all NBN member laboratories. 212 registrants representing 27 states were trained (FA B).
- **LRN Technical Meetings:** APHL facilitated virtual Laboratory Response Network for Chemical Threats (LRN-C) Biannual Technical Meetings in Fall 2020 and Spring 2021 which trained 611 attendees from almost every LRN-C laboratory. In Fall 2022, the LRN-C Technical meeting returned to an in-person format, training 117 attendees representing 30 LRN-C state programs and 20 vendors -- the highest attendance for an in-person meeting (FA B).

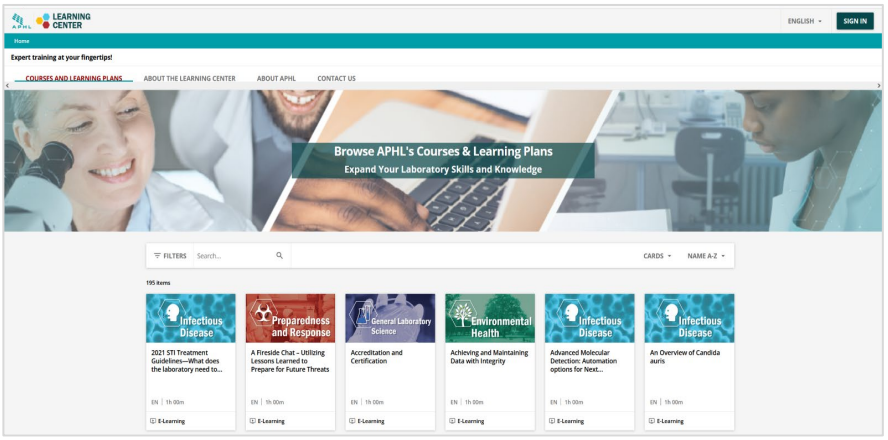
- **High Resolution Mass Spectrometry (HRMS) Survey:** APHL launched a comprehensive survey of PHLs on HRMS capability and capacity. After the publication of the survey report, APHL, in coordination with CDC, published a Request for Proposals to directly fund PHL HRMS capability and capacity improvements (FA B).



- **CaliciNet:** APHL continued to support the CaliciNet Outbreak Support Center sites by virtually convening the 11th CaliciNet Workshop to train laboratory professionals. APHL also supported attendance to the fall 2022 CaliciNet Workshop in Atlanta and offered 29 Professional Acknowledgment for Continuing Education (P.A.C.E) credits for the event (FA C).
- **National Center for Immunization and Respiratory Diseases (NCIRD):** APHL continued to support the NCIRD's respiratory virus work globally, conducting 14 influenza laboratory assessments, and convening five Next Generation Sequencing (NGS) and bioinformatics trainings on influenza and SARS-CoV-2, and an influenza biosafety training. Training initiatives were held in Thailand, Ghana, Panama, Algeria and India with representation from 37 countries (FA D).
- **Hepatitis C Virus (HCV):** APHL and the Division of Viral Hepatitis held a virtual HCV Diagnostics Workshop to discuss diagnostic needs and priorities required for hepatitis C elimination. The meeting included physicians, laboratory leaders, diagnostic developers and surveillance experts and led to a series of recommendations on diagnostic needs. The findings of the meeting were published and a journal supplement on the topic is in development (FA D).
- **NBS Workforce:** APHL's NBS Workforce Taskforce focused on staffing needed for US NBS programs to operate at higher performance levels. NBS program staffing needs are often different than other areas of PHLs, and NBS laboratory staff consistently report high levels of burnout due to a heavier workload, even before the COVID-19 pandemic. The Taskforce successfully conducted focus groups and will begin discussions on increasing staffing (FA F).

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

- **Training Webinars:** Approximately 7,100 learners attended live or archived webinars on the newly established APHL Learning Center, a new learning management system to deliver training activities. At least 90% of learners found the content relevant to their learning needs (FA I).
- **Fellowships and Internships:** APHL accepted 622 fellow applications and 258 mentor applications for the reinvigorated Public Health Laboratory Fellowship Program. From these, 136 fellows were supported across eight program areas and placed in 55 unique host laboratories across 35 states and the District of Columbia (FA I).



- **Board Examination Boot Camp:** Two cohorts participated in the Board Examination Boot Camp, a program that helps PHL staff prepare for board certification exams. Live sessions averaged 30-50 participants per session, and at least 10 participants reported passing the American Board of Bioanalysis or American Board of Medical Microbiology exams (FA I).
- **Laboratory Leaders of Today (LLOT):** In 2022, APHL revitalized and restructured the New Laboratory Director Orientation, which had not been offered since 2017. Renamed the LLOT, 65 laboratory directors and deputy/assistant directors from 55 PHLs in 32 states, territories and provinces who entered their roles in 2020 or later, engaged in virtual and in-person sessions to discuss critical topics and engage in peer-to-peer learning (FA I).

- **Emerging Leader Program (ELP):** 40 participants graduated from the ELP across four separate cohorts, which met virtually due to the COVID-19 pandemic. In July 2022, the program returned to a hybrid format and enlisted a fifth cohort of 19 participants. In total, staff from 33 PHLs in 22 states, territories and provinces participated in the program (FA I).

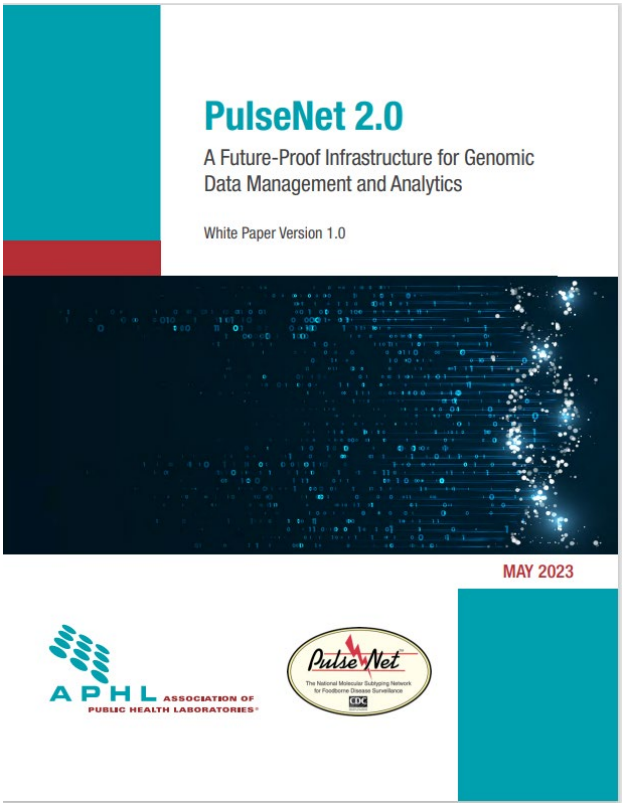
- **Workforce Surveys:** Knowledge Management Committee led the launch of the 2022 PHL Workforce Profiles, a bi-annual survey that is a complement to the Association of State and Territorial Health Officials and de Beaumont Foundation's Public Health Workforce Interests and Needs Survey. The PHL Workforce Profiles survey captured topics such as employment, education/training, recruitment and retention, satisfaction, and demographics with 1,464 responses received from 51 states and territories, including Washington D.C. (FA I).
- **Academic Partnerships:** In 2022, APHL created a new program to support the recruitment and retention of the PHL workforce by fostering collaborative partnerships between academic institutions and PHLs. Initial efforts focused on promoting the Career Pathways Fellowship and Internship programs, especially among minority-serving institutions, and developing tools to gather contact information and enable tracking on past and upcoming outreach event successes. (FA I).
- **Metagenomics Capability and Capacity:** APHL successfully executed Implementation of a Threat Agnostic Sentinel Surveillance Pilot with PHLs. This ongoing project aims to (1) build pathogen agnostic metagenomics workflows to support early warning and identification of public health threats, and (2) provide public health partners the ability to implement these workflows for targeted surveillance, outbreak investigation, and eventually clinical diagnostics (FA G).

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

- **PulseNet and Culture-Independent Diagnostic Tests (CIDTs):** APHL developed a national plan with the Division of Foodborne, Waterborne and Environmental Diseases to address culture-independent diagnostic testing and its impact on current laboratory-based surveillance programs such as PulseNet and the National Antimicrobial Resistance Monitoring System (FA C).

- **PulseNet 2.0:** In collaboration with the Enteric Diseases Laboratory Branch, APHL oversaw the development and implementation of PulseNet 2.0 focus groups to provide input about the new analysis platform, potential barriers to adoption and visions of the future (FA C).

- **Quality:** APHL, in collaboration with CDC, continued to work on completing documentation to cover all 12 of the NGS Quality Management System Essentials, producing over 80 documents. Additionally, the Laboratory Systems and Standards committee supported the development of seven quality tools related to model practices, including the first-of-its-kind Clinical Laboratory Improvement Amendments (CLIA) Internal Audits guidance document (FA C).



- **APHL Informatics Messaging Services (AIMS):** The AIMS platform hosted CDC's COVID-19 electronic laboratory reporting (CELR) data lake. CELR represented the effort to onboard jurisdictions to the AIMS platform to transmit all positive and negative test results via HL7 or CSV with the end goal of daily transmission. APHL made multiple enhancements to the AIMS platform to ensure that data are sent securely and are available and accessible to all partners when needed (FA E).

- **Electronic Case Reporting (eCR):** APHL partnered with CDC and the Council of State and Territorial Epidemiologists to rapidly accelerate implementation of eCR with the development of the eCR Now Fast Healthcare Interoperability Resources (FHIR) Application (App) which allowed healthcare organizations to implement eCR more readily for COVID-19. The app allowed thousands of healthcare organizations in over 50 jurisdictions to implement eCR for COVID-19 reporting (FA E).

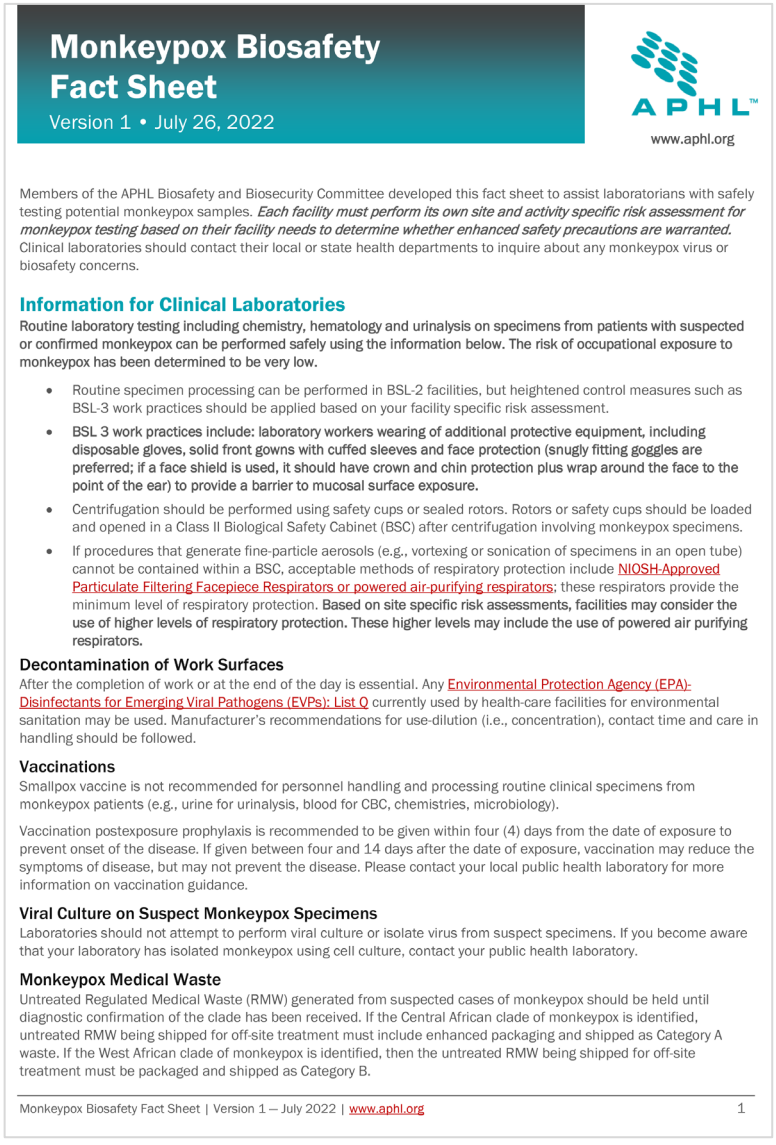
eCR Now FHIR App

HIGHLIGHTS: SUCCESSES FROM PERFORMANCE MEASURE NARRATIVES

- **Electronic Laboratory Reporting (ELR):** Through funding administered by APHL, five LRN-B and six LRN-C laboratories implemented ELR to CDC during the first half of the cooperative agreement. As of December 2022, 21 LRN member PHLs (13 LRN-B and eight LRN-C) have completed their ELR implementations using cooperative agreement funds (FA G).

- **Quality and Safety Systems Webinars:** APHL delivered six biosafety and biosecurity-related webinars addressing timely topics such as biosafety for new technologies during the COVID-19 response, and guidance for Ebola and Mpox (monkeypox) responses. These webinars reached over 3,300 laboratory professionals in public health and private clinical laboratories (FA H).

- **Public Health Laboratory System Database (PHLSD):** The PHLSD is an online, secure, comprehensive data repository, and the only national data repository that houses test capabilities, equipment inventory and unique laboratory profiles (e.g., facilities, data management, accreditations). Eleven new resources were developed to support 349 users and has been visited with 2,552 unique page views (FA H).



Monkeypox Biosafety Fact Sheet

Version 1 • July 26, 2022

APHL™ www.aphl.org

Members of the APHL Biosafety and Biosecurity Committee developed this fact sheet to assist laboratorians with safely testing potential monkeypox samples. *Each facility must perform its own site and activity specific risk assessment for monkeypox testing based on their facility needs to determine whether enhanced safety precautions are warranted.* Clinical laboratories should contact their local or state health departments to inquire about any monkeypox virus or biosafety concerns.

Information for Clinical Laboratories

Routine laboratory testing including chemistry, hematology and urinalysis on specimens from patients with suspected or confirmed monkeypox can be performed safely using the information below. The risk of occupational exposure to monkeypox has been determined to be very low.

- Routine specimen processing can be performed in BSL-2 facilities, but heightened control measures such as BSL-3 work practices should be applied based on your facility specific risk assessment.
- BSL 3 work practices include: laboratory workers wearing of additional protective equipment, including disposable gloves, solid front gowns with cuffed sleeves and face protection (snugly fitting goggles are preferred; if a face shield is used, it should have crown and chin protection plus wrap around the face to the point of the ear) to provide a barrier to mucosal surface exposure.
- Centrifugation should be performed using safety cups or sealed rotors. Rotors or safety cups should be loaded and opened in a Class II Biological Safety Cabinet (BSC) after centrifugation involving monkeypox specimens.
- If procedures that generate fine-particle aerosols (e.g., vortexing or sonication of specimens in an open tube) cannot be contained within a BSC, acceptable methods of respiratory protection include NIOSH-Approved Particulate Filtering Facepiece Respirators or powered air-purifying respirators; these respirators provide the minimum level of respiratory protection. Based on site specific risk assessments, facilities may consider the use of higher levels of respiratory protection. These higher levels may include the use of powered air purifying respirators.

Decontamination of Work Surfaces

After the completion of work or at the end of the day is essential. Any Environmental Protection Agency (EPA)-Disinfectants for Emerging Viral Pathogens (EVPs): List Q currently used by health-care facilities for environmental sanitation may be used. Manufacturer's recommendations for use-dilution (i.e., concentration), contact time and care in handling should be followed.

Vaccinations

Smallpox vaccine is not recommended for personnel handling and processing routine clinical specimens from monkeypox patients (e.g., urine for urinalysis, blood for CBC, chemistries, microbiology).

Vaccination postexposure prophylaxis is recommended to be given within four (4) days from the date of exposure to prevent onset of the disease. If given between four and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. Please contact your local public health laboratory for more information on vaccination guidance.

Viral Culture on Suspect Monkeypox Specimens

Laboratories should not attempt to perform viral culture or isolate virus from suspect specimens. If you become aware that your laboratory has isolated monkeypox using cell culture, contact your public health laboratory.

Monkeypox Medical Waste

Untreated Regulated Medical Waste (RMW) generated from suspected cases of monkeypox should be held until diagnostic confirmation of the clade has been received. If the Central African clade of monkeypox is identified, untreated RMW being shipped for off-site treatment must include enhanced packaging and shipped as Category A waste. If the West African clade of monkeypox is identified, then the untreated RMW being shipped for off-site treatment must be packaged and shipped as Category B.

Monkeypox Biosafety Fact Sheet | Version 1 — July 2022 | www.aphl.org 1

- **Biosafety Resources:** APHL produced seven biosafety resources to not only assist PHLs in responding to threats but to strengthen biosafety in clinical laboratories. Subjects included Mpox virus biosafety, clinical laboratory risk assessments, COVID-19 antigen testing biosafety guidance, a PHL risk assessment template for Ebola testing, and others (FA H).

- **Regional Consortia:** APHL supported seven regional consortia across the US, identifying needs and resources and sharing outcomes with the larger public health laboratory community through 139 individual and joint conference calls, five peer-to-peer exchanges, two tabletop exercises, and new packing and shipping resources (FA H).

For more information on the OE20-2001 Cooperative Agreement, please visit: www.cdc.gov/csels/dls/funding/announcements/oe20-2001/
For questions, please email CLSREvaluation@cdc.gov or info@aphl.org
Data Source: Year 1, 2 and 3 performance measure data and annual progress reports submitted by APHL.
Last updated 4/2024