March 18, 2021

Dear ELC Grantee Public Health Laboratory Directors:

APHL is pleased to provide a guidance tool to assist you in responding to the “Epidemiology and Laboratory Capacity for Infectious Diseases (ELC)” notice of funding opportunity (NOFO), which was released on February 24, 2021. The NOFO solicits applications for fiscal year 2022 funding for current ELC grantees under NOFO number CDC-RFA-CK19-1904. The application must be submitted by May 1st, 2021.

Your responses should include requests for continuation from projects that are cross-cutting (non-categorical) ELC projects (Section 1), emerging infectious disease programs (Section 2) and infectious disease activities (Section 3).

APHL encourages our members to be highly involved in the ELC grant writing process. Laboratory Directors and appropriate technical staff should contribute to the relevant sections of the grant proposal. Laboratory Directors are asked to share this guidance with appropriate technical staff. Once the application process is complete, summary comments and the budget markups will be sent to the ELC Governance Team members in each state/jurisdiction. If you are not the laboratory representative on the ELC Governance Team, please ensure that your laboratory representative shares this information with you.

If you need assistance, please feel free to contact the APHL staff below.

Sincerely,

Scott Becker, MS
Executive Director

APHL Staff Contacts

<table>
<thead>
<tr>
<th>Subject Area</th>
<th>Staff Contact</th>
<th>Email</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious Diseases</td>
<td>Kelly Wroblewski</td>
<td><a href="mailto:kelly.wroblewski@aphl.org">kelly.wroblewski@aphl.org</a></td>
<td>240-485-2728</td>
</tr>
<tr>
<td>Food Safety/PulseNet</td>
<td>Shari Shea</td>
<td><a href="mailto:sharon.shea@aphl.org">sharon.shea@aphl.org</a></td>
<td>240-485-2777</td>
</tr>
<tr>
<td>Waterborne Disease</td>
<td>Julianne Nassif</td>
<td><a href="mailto:julianne.nassif@aphl.org">julianne.nassif@aphl.org</a></td>
<td>240.485.2737</td>
</tr>
<tr>
<td>Health Information Systems</td>
<td>Michelle Meigs</td>
<td><a href="mailto:michelle.meigs@aphl.org">michelle.meigs@aphl.org</a></td>
<td>240-485-2771</td>
</tr>
</tbody>
</table>
Important Changes:

- **Budget Period (BP2)** application process was streamlined last year and will continue this year for BP3. Workplan milestones monitoring that has been done quarterly in REDCap will continue to serve in meeting the budget period progress reporting requirements.
- **Please include a brief statement at the beginning of the “Implementation Plan” for any/all activities that have been impacted due to the COVID-19 response.**
- **Thirty-two million dollars in new funding is available for wastewater surveillance for SARS CoV-2, including building capacity for laboratory testing, in Section II, F.**
- APHL maintains a list of manufacturer discounts for public health on our website: Public Health Pricing List
- **C2: Data Modernization:** APHL has reiterated many of the DMI suggested activities from our 2020 guidance to provide general guidance and information based on the original intent and fundamental focus areas of DMI. However, PHLs are strongly advised to work with their ELC project officer and the ELC HIS team (edx@cdc.gov) to ensure alignment of these resources with required activities funded under the Coronavirus Response and Relief Act, 2021.

Section 1: Cross-cutting Emerging Infectious Disease Capacity, Systems and Leadership

(Guidance includes only sections relevant to the laboratory)

Attachment A: Cross-Cutting Epidemiology and Laboratory Capacity (p. 9-22)

- 64 Awards; average of $345,313 per award, total availability of funds: $22,100,000
  
  To build and maintain epidemiological and laboratory capacity, funds should be used for personnel, supplies, travel, systems, statistical software and other requisite.

  APHL suggests that you include activities that will improve integration with your health department partners, will broadly improve your laboratory practice, and will benefit testing activities across ELC-funded programs. Although activities are combined be sure to submit a SEPARATE LABORATORY BUDGET.

- Additional $5,400,000 to support for AMD:
  1. AMD-related workforce development through training at the state and local level for training leads or training participants
     Training leads: Approximate number of awards: 7; average of $20,000 to $150,000
     Training participants: Approximate number of awards: 40 to 64, average $3,000 to $10,000
  2. Bioinformatics support
     Approximate number of awards: 7; average of $50,000 to $150,000
  3. Support state and local health department initiatives to extend the use of AMD technologies
     Approximate number of awards: 20 to 40; average of $15,000 to $100,000
CDC may have additional funding beyond what was detailed in the original continuation guidance. All eligible laboratories should consider proposing activities in this section and consider proposing greater requests than typical. CDC is looking to focus funding requests to expand workforce and increase sequencing capacity so prioritize requests for additional staff and equipment that will increase capacity or throughput. Please note that these additional AMD funds may not be awarded through this funding mechanism.

Strategies and Activities:

Area A: Surveillance, Detection and Response

1) Enhanced Workforce Capacity

APHL Suggested Activities

- Consider your need for training in disease areas traditionally funded through ELC or biosafety. A list of upcoming training opportunities offered by APHL’s Training Program can be found here (Strategy 1c)
- Consider including travel to other public health laboratories to receive training.
- Consider AMD workforce there are two tiers that applicants may apply to - requests under both tiers will be considered:
- **AMD Workforce:**
  - All laboratories request funding for training for current staff including travel for staff to attend regional trainings held by workforce training leads. Other costs related to AMD training and workforce development with accompanying justification may also be considered.
  - CDC will consider support for travel to conferences including InFORM 2022. Dates and location are TBD.
- **AMD Regional Workforce Development Training Lead:**
  - Given the uncertainty of travel, training lead laboratories should consider asking for additional funding to support technologically advanced online training and other technology that would assist with providing services around training
- **AMD Regional Bioinformatics Regional Resource:** Laboratories interested in providing bioinformatics resources and support to other public health laboratories in their region should apply. Funding requests should include:
  - One full-time bioinformatics staff member, who serves as the bioinformatics subject matter expert for the entire region.
  - Staff may be contracted through an academic partner or other organization; funding may be requested for the time, the costs of acquiring and implementing contract services for the personnel member.
  - Travel costs associated with the BRR providing consultation throughout the defined region, including on-site visits with regional public health laboratories and health departments.
  - Successful activities of current BRRs include: hosting online classes, providing virtual machines and computing resources, one-on-one visits with PHLs, supporting genome assembly and analysis and ad hoc technical services. In
addition to bioinformatics expertise, the resource supports also provided assistance in communication with PHL information technology departments. Laboratories without in-house bioinformatics expertise have also contracted with academic institutions to help provide technical expertise.

2) Enhance Investigation and outbreak response

- Consider the costs associated with setting up or supporting an existing courier system for the transport of ELC-funded organisms.
- Consider requesting funds to implement the CIFOR Outbreaks of Undetermined Etiology (OUE) Guidelines
- Work with epidemiology partners to identify needs to sustain or implement testing to support outbreak response.

4) Strengthen laboratory testing for response

**APHL Suggested Activities**

- **Implement, sustain or enhance testing to support infectious disease surveillance or outbreak response.** When developing these activities consider the following:
  - A number of nucleic acid extraction platforms commonly used in public health laboratories will be sun setting in coming years. Consider your need to update extraction platforms and consult this table for information on which platforms are sun-setting and which CDC assays have been cleared or evaluated on various models.
  - APHL maintains a list of manufacturer discounts for public health on our website: [Public Health Pricing List](#).
  - Consider your need for miscellaneous laboratory supplies such as packaging and shipping containers (plus shipping costs), viral transport media, culture media, PPE (including N-95s), commercial PCR reagents, nucleic acid extraction chemistries, pipettes/pipet tips.
- **AMD Capacity Building:**
  - This year ALL LABORATORIES are encouraged to submit a budget to build AMD capacity. Laboratories are encouraged to include requests for staffing, equipment and computing infrastructure required to support robust and flexible sequencing capacity. These requests may not be awarded with this continuation request but additional supplemental opportunities may be forthcoming.
  - Laboratories are encouraged to request funding for liquid handlers and other equipment to support automation.
  - Laboratories are encouraged to request funding for additional sequencers and other instrumentation to increase the amount of sequencing capacity.
  - Requests around additional supplies and equipment to aid in the set-up of AMD technology with little to no existing infrastructure.
• Funding requests for additional laboratory staffing will also be considered.
• Requests for additional computing infrastructure needs either local or cloud resources are also encouraged.

5) Improve laboratory coordination and outreach to improve efficiency

• Consider establishing partnerships with clinical and commercial laboratories to develop or enhance cross-cutting specimen and data sharing networks to enhance and create efficiencies amongst existing surveillance activities. Especially consider the benefit for influenza and other respiratory pathogens, antimicrobial resistant isolates, Culture independent diagnostic tests, and foodborne specimens/isolates. Consider including activities that will enhance partnership for multiple pathogens.

Attachment B: ELC Leadership, Management and Administration (p. 22-25)

Estimated number of awards for ELC Annual Meeting: 64; average per award: $6,000 for travel
Estimated number of awards for Personal: 43; average per award: $90,000 for personnel and associated costs
Estimated number of awards for ICEID: 64; average per award: $1,550 per traveler; $4,650 total for 3 travelers

Consider requesting funds to support a Lab-Epi Connector (an epi liaison) that is housed at your laboratory. This person would enhance and help support ongoing communication between lab and epi and clinical laboratory partners. (Strategy 1b or 1c)

Applicants are required to include travel support to attend the 2022 ELC Annual meeting in Atlanta.

Applicants should request assistance to support travel to the March 2022 International Conference on Emerging Infectious Diseases (ICEID) to be held March 6-9, 2022 in Atlanta, GA.

Attachment C: Health Information Systems Capacity (p. 26-34)

• 64 Awards; average of $438,000 per award, total availability of funds: $28,000,000

Strategy 1: Advance Electronic Data Exchange - Activity D: Advance electronic data exchange for Public Health Laboratories

Strategy 2: Sustain and enhance information systems. Activity A: Maintain existing information systems and Activity Cii: LIMS

APHL Suggested Activities

• Consider requesting funds to attend the following conferences or meetings:
  • Request additional funds (above those required under Attachment B) for Informatics leads to attend the 2022 ELC Annual meeting in Atlanta.
  • 2021 APHL Annual Meeting
• LOINC Laboratory Conference: https://loinc.org/meetings/
• American Health Information Management Association (AHIMA) Health Data and Information Conference, September 20-22, 2021 Virtual Conference https://conference.ahima.org/

• Ensure resources are available to review current and new informatics policies and distributed guidance to ensure PHLs stay up to date on changing regulations and expectations such as the 21st Century Cares Act.

• Consider requesting funds for membership dues or rights to maintain access to relevant Informatics data exchange standards such as Health Level 7 (HL7).

• Consider requesting funds to retain or hire a laboratory interoperability program manager as the PHL liaison to the legal department, information security groups, and agency leadership. This resource would be responsible for coordinating and leading prioritization efforts by analyzing current informatics activities, and identifying resource gaps to support ELC activities. This position could be a shared resource between the public health agency and laboratory to enhance epi-lab coordination.

• Consider requesting funds to retain or hire a laboratory interoperability technical lead. This resource coordinates the plan of action for establishing and maintaining laboratory data exchange capabilities for ELC focus activities. Serving as the PHL liaison to the information technology department, system vendors, data exchange partners, national standards groups and organizations, APHL technical assistance teams as well as internal laboratory and epidemiology subject matter experts.


• Request funding to maintain access to the skills and tools necessary to map, create, validate, maintain and enhance standardized laboratory vocabulary code sets and LIMS configuration such as:
  • LOINC to Vendor IVD Test Result (LIVD) mapping standards to ensure the proper codes are assigned when configuring or updating laboratory tests within information systems.
  • IHE Laboratory Analytical Workflow (LAW) profile: https://ivdconnectivity.org/law-profilehttps://www.ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_TF_Vol2b.pdf: Implement either in the LIMS or via a middleware to support a standard interface to multiple instruments. When purchasing new instruments, PHLs should assess whether the vendor supports the LAW profile.
  • Research skills and importance of adopting HL7 FHIR Resources in anticipation of modernization initiatives: http://hl7.org/fhir/dstu2/uslab/uslabreport.html
• Request funding to maintain access to the skills and tools necessary to properly format, route and transmit laboratory data to support inter and intra jurisdictional data exchange needs. PHLs should consider costs of tools and skills necessary to advance data transport and routing activities such as:
  • Implementing data validation tools to support enhanced data completeness, timeliness, and specificity. Impact: by applying standard definitions and business rules within the logical system architecture via an integration broker, a front-end validator can prepopulate tables, ensure data transparency, require that key fields are populated, automatically flag message inaccuracies, and improve the overall quality of processed data.
  • Data Integration Engines: PHL should assess access to and availability of shared data integration engine expertise and tools. The lab should assess upcoming projects associated with data exchange and to determine funding is required for additional expertise or integration tool licenses to ensure PHLs have the access they need to meet project goals.
  • Consider requesting funds to review and expand message data transport options beyond PHINMS. Options include: web services, Direct, SFTP, S3 and/or other protocols as appropriate. Technical assistance to support these different transport options may be available upon request through the APHL technical assistance program.

• Maintain current CDC program data feeds and participate in efforts to enhance the quality and completeness of these data including:
  • PHLIP: Electronic Laboratory Surveillance Feed from laboratories to CDC in support of respiratory routine and outbreak test results (Influenza, NREVSS data, SARS-CoV-2, VPD messaging for regional PHLs).
    ▪ Migrate PHLIP reporting to the current HL7 2.5.1 message standard
    ▪ Capture ILINet provider information and other epidemiologically important information in LIMS, and add to PHLIP message
    ▪ Reporting non-influenza respiratory virus surveillance data automatically through PHLIP to replace manual reporting to the National Respiratory and Enteric Virus Surveillance System.
  • ARLN: Implementation and continued maintenance of HL7 messaging to CDC using the Data for Action on Antibiotic Resistance Threats (DAART) platform
  • APHL Technical Assistance is available to assist with message upgrades, enhancements, and data transport efforts. For more information about technical assistance or for access to the PHLIP or ARLN encoding guidelines, please email the Informatics Help Desk at informatics.support@aphl.org.

• PHLs are strongly advised to work with their ELC project officer and the ELC HIS team (edx@cdc.gov) to ensure alignment of these activities with required activities funded under the Coronavirus Response and Relief Act, 2021 and Attachment C2: Data Modernization. The PHL required activities outlined under CARES Act supplemental dollars include:
  • Employ a well-functioning Laboratory information Management System (LIMS) to support efficient data flows within the PHL and its partners.
  • Ensure ability to administer LIMS
  • Interface diagnostic equipment to directly report laboratory results into LIMS
• Deploy a web portal in place to support online ordering and reporting. Integrate the web portal into the LIMS
• Enhance laboratory test ordering and reporting (ETOR) capability*

• *Opportunity: During this budget period, the APHL informatics program will focus heavily on standards-based Electronic Test Order and Result in alignment with data modernization goals to improve the timeliness, flexibility, and mobility of data, while reducing the financial and security risks of implementing local solutions.

  • The Informatics Program is currently conducting a landscape analysis of ETOR capabilities – if you have not already participated, please reach out to Rachel Shepherd: Rachel.shepherd@aphl.org. The assessment focuses on the capacity and capability areas needed to meet ETOR data modernization goals. APHL and CDC will use these assessment data to identify ETOR-related funding opportunities and APHL technical initiatives to support member laboratories.

  • Through the APHL/CDC cooperative agreement and based on stakeholder input, the Informatics program will develop a technical assistance model and deploy a set of shared cloud-based tools and resources to support a common standards based ETOR initiative focused on data connectivity, routing, and vocabulary management services through the AIMS platform. (see Attachment C: Health Information Systems Capacity, Strategy 2: Sustain and enhance information systems, Activity Cii: LIMS: Enhance system to enable the automated processing and use of HL7 electronic test orders that are received and to create HL7 test orders and Attachment C2: Data Modernization, Strategy 2, Activity 2b: “Accelerate improvements to data quality, exchange, management, and use”. PHLs interested in participating in and contributing to a common model for PHL standards based ETOR are encouraged to contact the informatics program: informatics@aphl.org

Attachment C2: Data Modernization (p. 35-41)
• 64 awards, average of $195,000 per award, total availability of funds: $12,500,00

AREA A: Accelerating Data Modernization

External Links and Resources

• CDC’s public health data strategy and IT transformation efforts
• CDC DMI Logic Model
• CDC DMI Goal Infographic
• CDC IT Strategic Plan (2019-2021)
• CDC Open Technology
• APHL Informatics Program
• APHL Health IT Training Information
• APHL Informatics Competencies to ELC crosswalk- not specific to C2
• Informatics Self Assessment Tool_pdf version
• H.R.5321 - Public Health Infrastructure Modernization Act of 2019
• Healthy People 2020 alignment: Health Communication and Health Information Technology
• Healthy People 2020 alignment: Public Health Infrastructure

Overview/Information:

• APHL’s Informatics program and the Informatics committee is committed to supporting the data modernization initiatives of our members and federal partners and is beginning to stand up technical
and programmatic initiatives that will benefit and enhance these efforts. As such, PHLs should consider assigning both a programmatic and technical point of contact to serve as liaisons to the APHL informatics program.

- The activities funded under Data Modernization are not limited to infectious disease program areas. PHLs should identify holistic, innovative approaches to advance laboratory data management workforce, systems, tools, and processes and are encouraged to review and link evaluation measures and outcomes to the overall CDC Data modernization logic model.

- APHL has reiterated many of the DMI suggested activities below from our 2020 guidance to provide general guidance and information based on the original intent and fundamental focus areas of DMI. However, PHLs are strongly advised to work with their ELC project officer and the ELC HIS team (edx@cdc.gov) to ensure alignment of these resources with required activities funded under the Coronavirus Response and Relief Act, 2021. The PHL required activities outlined under supplemental dollars include:
  - Employ a well-functioning Laboratory information Management System (LIMS) to support efficient data flows within the PHL and its partners.
  - Employ a well-functioning Laboratory information Management System (LIMS) to support efficient data flows within the PHL and its partners.
  - Ensure ability to administer LIMS
  - Interface diagnostic equipment to directly report laboratory results into LIMS
  - Deploy a web portal in place to support online ordering and reporting. Integrate the web portal into the LIMS
  - Enhance laboratory test ordering and reporting (ETOR) capability*

*Opportunity: During this budget period, the APHL informatics program will focus heavily on standards-based Electronic Test Order and Result in alignment with data modernization goals to improve the timeliness, flexibility, and mobility of data, while reducing the financial and security risks of implementing local solutions.

- The Informatics Program is currently conducting a landscape analysis of ETOR capabilities – if you have not already participated, please reach out to Rachel Shepherd: Rachel.shepherd@aphl.org. The assessment focuses on the capacity and capability areas needed to meet ETOR data modernization goals. APHL and CDC will use these assessment data to identify ETOR-related funding opportunities and APHL technical initiatives to support member laboratories.

- Through the APHL/CDC cooperative agreement and based on stakeholder input, the Informatics program will develop a technical assistance model and deploy a set of shared cloud-based tools and resources to support a common standards based ETOR initiative focused on data connectivity, routing, and vocabulary management services through the AIMS platform. (see Attachment C: Health Information Systems Capacity, Strategy 2: Sustain and enhance information systems, Activity Cii: LIMS: Enhance system to enable the automated processing and use of HL7 electronic test orders that are received and to create HL7 test orders and Attachment C2: Data Modernization, Strategy 2, Activity 2b: “Accelerate improvements to data quality, exchange, management, and use”.

PHLs interested in participating in and contributing to a common model for PHL standards based ETOR are encouraged to contact the informatics program: informatics@aphl.org
Strategy 1: Understand, coordinate, and lead data modernization efforts in the jurisdiction

Activity 1a: Lead and coordinate data modernization efforts in the health jurisdiction

Applicants must designate an individual or group of people responsible for leading data modernization efforts throughout the budget period. Applicants may assign a single data modernization lead or choose a team approach to meet this requirement.

Activity 1b: Document and understand workforce, data, and health information system needs and opportunities

- **Activity 1.b.i** focuses on gaining situational awareness of laboratory informatics capacity and capabilities by documenting and baselining current strengths, weaknesses and gaps across technologies, infrastructure, policies and procedures and skill sets.

- The outcomes of activity 1.b.i will inform activity 1.b.ii which focuses on the development of a data modernization roadmap that describes the future or desired state of laboratory information systems and workforce capabilities across the organization.

- This strategic roadmap should identify priority improvements, and value-add initiatives that target specific needs within the context of other national, interstate and intrastate modernization efforts.

- Consider requesting funds to conduct or expand a comprehensive analysis to assess the function, utility, and application of information systems, IT infrastructure, software packages, standards adoption, and tools across all laboratory workflows and business processes:
  - Test Requests and Sample Receiving
  - Specimen and Sample Tracking/Chain of Custody
  - Lab Information Management Systems (LIMS) across the enterprise- Legacy and new technologies
  - Test Results and Instrument Interfacing/Integration
  - Report Preparation and Distribution
  - Data Analysis, Knowledge Management
  - Interoperability and Data Exchange
  - Data Repositories

- Consider requesting funds to document and prioritize gaps and inefficiencies that must be addressed to meet the data modernization goals of creating scalable, modular, and sustainable public health data solutions that take advantage of shared services, and cloud computing strategies. Examples include:
  - Outdated IT infrastructure and system components
  - Inefficient, outdated or ineffective technologies
  - Data availability or quality issues
  - Underutilized technology
  - Gaps in technology adoption
  - Access to necessary tools (such as data integration engines)
  - Risks to continuity of operations and surge capacity
  - Missing, unclear or restrictive policies and procedures
• Consider retaining expertise to conduct an overall assessment of current laboratory informatics workforce competencies across strategic, operational, and technical roles, documenting strengths, weaknesses, and gaps.

• Consider conduction detailed job analysis activities to validate the key competencies and related concepts, skills, knowledge, and tools of those critical positions necessary to manage, implement, support, and maintain modernized laboratory informatics services. Although not inclusive, applicants may find useful information in this spreadsheet that maps informatics competencies to general ELC health Information System Capacity (C1) goals. [APHL Informatics Competencies to ELC crosswalk]

• Consider the use and applicability of the APHL Informatics Self-Assessment Tool (pdf or online) to support laboratory assessment activities. Please reach out to Rachel Shepherd (rachel.shepherd@aphl.org) for access to this tool.

• Consider requesting support for specific time-bound staff augmentation or targeted support through the Informatics Technical Assistance Program supported by CDC. All requests must be submitted to edx@cdc.gov for review and approval.

Strategy 2: Accelerate data and health information system modernization

Activity 2a: Implement workforce enhancements to accelerate data modernization

• Consider requesting funding to send key staff to relevant conferences and trainings to fill an identified skill gap to support current or future modernization initiatives. Applicants may find ideas or relevant information on this compiled list of resources: [APHL Health IT Training List]

• Leverage existing laboratory consortiums and consider requesting travel and meeting costs to convene and discuss interstate coordination and peer-to-peer informatics learning opportunities.

• Consider requesting support for specific time-bound staff augmentation or targeted support through the APHL Informatics Technical Assistance Program supported by CDC. All requests must be submitted to edx@cdc.gov for review and approval.

• Consider requesting funds to develop basic Informatics training for PHL staff using current and upcoming materials co-developed by CDC and APHL.
  • Introduction to Laboratory Informatics Course: Life of a Specimen
  • Introduction to Laboratory Informatics Course: Life of a Result
  • Competency Guidelines for Public Health Laboratory Professionals. See Table 11 for Informatics domain and Table 14 for Bioinformatics domain: [https://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm#tab14]

Activity 2b. Accelerate improvements to data quality, exchange, management, and use

• Applicants are highly encouraged to request funding to support innovative, forward thinking project proposals to support laboratory data modernization goals.
Attachment D: Impact and Evaluation (p. 42-44)
- 4 awards, average of $125,000 per award, total availability of funds: $500,000

Attachment E: Cross-Cutting Emerging Issues: Enhanced Surveillance, Outbreak Investigation Response and Reporting, Surge Efforts and Interventions (p. 45 – 47),
- plan for $3,000,000; will only be funded in emerging situation
- Funds will only be available in the event of a local or national infectious disease outbreak. All proposals should plan for a request $3,000,000 (small jurisdictions may request less while very large jurisdictions may request more). This request will likely be marked “approved but unfunded” in your initial budget markup, but it will expedite the release of funds should outbreak conditions warrant.

Section II: Emerging Infectious Disease Capacity, Systems, and Leadership

- 56-59 awards; average of $575,000 per award, total availability of funds: $33,000,000; excluding NWSS
- 35 awards; average of $900,000 per award, total availability of funds: $32,000,000; NWSS funding estimates

- APHL strongly encourages you to reach out to your state ELC foodborne epidemiologists and PI to discuss funding for whole genome sequencing to support PulseNet and other foodborne activities.

- It is important to develop and write to a comprehensive strategy for conducting any of the surveillance activities listed in Tier I, Tier II, Tier III, as applicable. This includes justification of personnel/staffing for performing these activities and requesting enough equipment, supplies and reagents to conduct surveillance for all foodborne and waterborne programs. Of note, CDC does not plan to fund any traditional biochemical, serotyping or PFGE reagents and supplies since the primary characterization and subtyping method for PulseNet is WGS.

- As a reminder, PulseNet’s turn-around time for WGS is 7 working days from date the isolate was received (or recovered) in the public health laboratory to the date of upload to the national database. Funding for personnel, supplies, equipment and reagents should reflect the laboratory’s ability to meet this turn-around time.

- To estimate costs for WGS, consider $125/isolate. Include costs associated with sequencing PulseNet certification, proficiency testing and validation isolates.

- If medium to high volume laboratories currently have only one MiSeq sequencer, it is highly suggested to request at least one additional MiSeq, MiniSeq or iSeq depending on your laboratory’s volume. PulseNet laboratories should strive to have at least two sequencers in the laboratory.

- If your laboratory is considered a small volume laboratory, it is highly suggested to request an Illumina iSeq sequencer to sequence PulseNet pathogens in a timely fashion.

- Include costs of service agreements for Illumina MiSeqs used to sequence PulseNet pathogens.

- Request funding to support equipment, supplies and personnel for isolate recovery of CIDT positive specimens.
Tier 1: Area A: Surveillance, Detection, and Response

2a. Enhance Laboratory Workforce Capacity

- **Request funds so that staff are trained in the protocols used by all projects under Attachment F, and when necessary, attend trainings such as at a PulseNet area lab, other peer PHL or CDC.**
  - Include funding to send at least one staff person to attend PulseNet MiSeq Workshop and one staff to attend PulseNet BioNumerics 7.6 workshop
  - Include funding for BioNumerics 7.6 license
  - Identify one designated POC for PulseNet, CryptoNet, NARMS, CaliciNet, waterborne testing, and Cyclospora genotyping
  - Ensure your laboratory signs and returns PulseNet, CryptoNet and CaliciNet MOU, CryptoNet and PulseNet ToR, and CryptoNet DUA documents
  - Participate in regularly scheduled calls, webinars, in-person trainings, etc.
- Participate in monthly PulseNet WGS calls facilitated by PulseNet
- Participate in area lab calls administered by PulseNet Area labs or APHL
- Participate in regular (e.g. weekly, monthly, etc.) CaliciNet meetings between epidemiology and laboratory staff to discuss norovirus outbreaks
- Participate in quarterly OutbreakNet/WASH webinars
- Participate in quarterly NARMS conference calls
- Request funding to send at least one PulseNet Laboratorian to attend InFORM 2022 Conference in spring of 2022. At this time, the location and dates have not been determined
- Travel to the annual CaliciNet User Meeting. At this time, the location and dates have not been determined.

5. Strengthen laboratory testing for response

- **Consider packaging and shipping costs for sending outbreak-related and specific NARMS-requested isolates to CDC for antimicrobial susceptibility testing.**

6. Enhance laboratory testing for surveillance and reporting

- **Consider WGS supply costs and expenses for maintaining sequencing personnel, equipment, and infrastructure to achieve goals of sequencing enteric pathogens using PulseNet methods.**
- **Request funding to purchase reagents and supplies in order to sequence all PulseNet pathogens in real-time. This includes:**
  - Automation/robotic instrumentation
  - Sequencers
  - Service contacts for equipment
  - Personnel necessary to support PulseNet surveillance activities
- **Request funding for equipment, supplies and personnel to support isolate recovery of CIDT positive specimens.**
• Request funding to enhance/maintain courier services for specimen transport from clinical laboratories to public health laboratories.

• Consider packaging and shipping costs for sending routine surveillance isolates to CDC for antimicrobial susceptibility testing, per the required NARMS performance metrics and the Enteric Disease Isolate Submission Table (located here: https://www.cdc.gov/ncezid/dfwed/edlb/index.html). **NOTE:** Deadlines and requested timing/frequency of routine surveillance isolate shipments may be affected by the COVID-19 response. Specific guidance will be provided by the CDC NARMS program as needed.

• Consider all costs for conducting laboratory-based surveillance, diagnostics and subtyping for PulseNet, CryptoNet, NARMS, CaliciNet and general surveillance and outbreak investigation functions, including waterborne diseases:

  • For PulseNet protocols, include funding for the following ancillary equipment:
    - Centrifuge, accommodating 1.5-2 ml tubes and up to 13,000-14,000 rpm
    - Heat block
    - Ice buckets/containers
    - Incubator (35-37°C)
    - Magnetic Stand-96 (ThermoFisher Cat# AM10027 or equivalent)
    - Microcentrifuge
    - Micropipettes, capable of volumes from 1 μl to 1000 μl. Single and multichannel (20 μl and 100μl volumes)
    - Microplate centrifuge or equivalent
    - NanoDrop 2000 UV-Vis/Nanodrop Onespectrometer or equivalent for determination of 260/280 nm readings
    - Pipet-aid
    - Qubit 2.0 or 3.0 Fluorometer or equivalent for quantification of double-stranded DNA
    - Thermal cycler, capable of accepting a 96-well plate, with heated lid
    - Vortex
    - -20°C and -80°C freezers and refrigerators
    - Water bath(s) or thermal block(s) accommodating 1.5 ml microcentrifuge tubes
    - **NOTE:** Two sets of pipettes are suggested; one for working with pre-amplified product and reagents and one set for working with post-PCR amplified product and reagents.
    - **OPTIONAL:** UPS back-up for the MiSeq (Recommended: Staples, Cyberpower AVR Series Line Interactive 1.5 kVA UPS, Cat# IM1M14018)
    - **OPTIONAL:** External encrypted hard drive or server for data transfer and storage if BaseSpace or networking of the instrument is not available (Suggested: CDW, DataLocker H350 Basic Hard Drive 1 TB USB 3.0, Cat# 4075102).

  • For CaliciNet, include funding for-
    - Personnel
    - Reagents and consumables for norovirus detection and sanger sequencing (or outsourcing, if applicable), freezer space for storing positive norovirus
specimens and norovirus negative specimens with viral epidemiology for three years.
  o Whole Genome Sequencing reagents for Next Generation Sequencing pilot labs.
  o Reagents for detection and sanger sequencing of sporadic norovirus specimens.
  o Specimen collection costs including providing kits, shipping and/or courier systems

• For CryptoNet
  • Include costs for collecting, screening and/or shipping Crypto positive clinical specimens to the CryptoNet Reference Laboratory at CDC for subtyping.

8. Improve laboratory coordination and outreach to improve efficiency

• Consider including personnel for Lab/Epi coordinator position to assist with data analysis, interpretation and reporting of clusters for outbreaks and routine surveillance

9. Advance electronic information exchange implementation

• Review APHL ELC guidance language included under Attachment C: Health Information Systems Capacity and Attachment C2: Data Modernization for general Informatics guidance.

Tier 2: Cryptonet

15. Enhance laboratory testing for response

• For CryptoNet certified sites-
  • Include costs for personnel, equipment and maintenance, software upgrades and laboratory supplies in order to 1) conduct near real-time subtyping for Cryptosporidium using CryptoNet protocols; 2) actively participate in evaluating and/or validating new methods, software modules and scripts.
  • Consider training and certification costs including travel to in-person workshops

• For CryptoNet Regional Laboratories:
  • Include costs for personnel to provide troubleshooting, training and analysis assistance for participants in your respective region.
  • Include personnel, equipment and maintenance, software upgrades and lab supply costs in order to provide surge capacity for participants in your respective region

16. Enhance laboratory testing for surveillance and reporting

Same as above, 15
**Tier 2: Cyclospora Genotyping**

17. Strengthen laboratory testing for response

- *Consider the costs of reagents, supplies, and equipment to implement or continue amplicon-based multilocus sequence typing methods to provide genotyping information for Cyclospora cayetanensis. CDC protocols are available upon request.*

- *Consider requesting funding to travel to training either at CDC or another public health laboratory.*

**Tier 2: Environmental Microbiology**

18. Enhance workforce capacity

- *Consider travel costs for environmental microbiology training at partner laboratories (CDC, EPA, public health, environmental or academic laboratories) and registration and travel to technical conferences to enhance skills and share knowledge.*

- *Consider joining the EPA Water Laboratory Alliance and participating in relevant exercises to assess response capabilities and identify areas for improvement.*

19. Enhance laboratory testing for response

- *Consider the cost of reagents, supplies and equipment for environmental microbiology test kits and culture. Consider the cost of equipment necessary to measure physiochemical water quality parameters (temperature, pH, electrical conductivity and dissolved oxygen).*

- *APHL recommends working with subject matter experts at CDC and local and state partners to develop metrics for environmental assessments associated with waterborne disease investigations.*

**Tier 2: FoodCore**

22. Enhance investigation and outbreak response

- *Note the requirement on pg 64 to participate in calls, meetings and site visits. FoodCORE will look for proposals that demonstrate a coordinated and comprehensive approach to the required work.*

23. Enhance laboratory testing for surveillance and reporting

- *Consider the necessary reagents and equipment to complete the enhanced public health laboratory surveillance strategies listed on pg 65.*
**Tier 2: FoodNet**

24. Enhance laboratory testing for surveillance and reporting
   - *Consider personnel, equipment and lab supplies needed in order to provide the following testing for FoodNet pathogens-
   - Develop laboratory capability for parallel testing by CIDT and culture for enteric pathogens with exclusion regulations from school, daycare, employment, and high risk settings
   - Develop laboratory capability for testing of emerging enteric pathogens
   - Conduct reflex culture on specimens/clinical material submitted for FoodNet cases
   - Conduct sequencing on enteric isolates based on prioritization schemes developed in collaboration with CDC NARMS and FoodNet epidemiologists
   - Linked laboratory (e.g., WGS, species, serotype, etc.) and epidemiologic data for FoodNet cases in collaboration with on-site FoodNet epidemiologists

   - *Consider storage costs for storing/preserving FoodNet isolates for future characterization

   - *Considers costs for traveling to the annual FoodNet Vision Meeting in order to lend a voice to laboratory related topics including the use and interpretation of CIDTs and WGS.

27. Advance electronic information exchange implementation

   - Review APHL ELC guidance language included under Attachment C: Health Information Systems Capacity and Attachment C2: Data Modernization for general Informatics guidance.

**Tier 2: NoroSTAT**

31. Improve surveillance and reporting

   - Ensure adequate personnel in order to sequence and report all laboratory-confirmed norovirus outbreaks to CaliciNet within 7 business days

**Tier 2: National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced**

32. Improve surveillance and reporting

   - Consider a funding request to standardize and electronically transmit norovirus data via the AIMS PHLIP data feed. Reporting non-influenza respiratory virus surveillance data automatically through PHLIP can replace manual reporting to the National Respiratory and Enteric Virus Surveillance System. The APHL Informatics Technical Assistance Team may be available to assist staff with updating and validating their standardized HL7 PHLIP messages to support NREVSS data exchange efforts. For more information about technical assistance for PHLIP, email informatics.support@aphl.org. See Attachment C: Health Information System for additional Informatics related guidance.
Tier 2: PulseNet Area Laboratories

36. Enhance laboratory testing for response

- Request funding to purchase reagents and supplies in order to assist with sequencing PulseNet pathogens requests within the region. This includes:
  - Personnel necessary to support PulseNet Area laboratory duties.
  - Reagents/supplies
  - Equipment
  - Resources for training (reagents, supplies)

- Request funding to support equipment, supplies and personnel for isolate recovery of CIDT positive specimens.

- Request funding to enhance/maintain courier services for specimen transport from public health laboratories within the region.

37. Enhance laboratory testing for surveillance and reporting

Same as above, 36

Tier 3 National Wastewater Surveillance System (NWSS) (p 73-75)

- 35 awards; average of $900,000 per award, total availability of funds: $32,000,000; NWSS funding estimates

- This imitative looks to expand wastewater surveillance in the National Wastewater Surveillance System (NWSS) [https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater-surveillance.html](https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater-surveillance.html), with the aim of understanding community disease prevalence.

- Applicants should note NWSS requires a separate budget template. Workplan progress reporting is required quarterly, consistent with other projects in Section F. Financial reporting of expenditures and unliquidated obligations is required monthly. This initial year of NWSS expansion is focused on detection of SARS CoV-2 in wastewater, however, CDC anticipates sustaining support for NWSS and expanding detection capabilities to include other pathogens with antimicrobial resistance being a likely future target.

- Jurisdictions with HHS wastewater surveillance contracts are eligible to apply for this funding but should choose sampling sites that complement, not duplicate that effort.

Requirements:

- Identify one or more points of contact as NWSS coordinators
- Identify one or more laboratory points of contact for wastewater testing

APHL recommends that public health laboratories strongly consider wastewater surveillance testing in their laboratories, and that they designate one or more points of contact to partner with their health department colleagues, APHL, NWSS members, wastewater treatment facilities and CDC.
Alternatively, health departments may contract with environmental agencies, commercial or academic partners for laboratory services.

- **Participate in NWSS calls, annual meeting and program site visits**
  APHL recommends that public health and environmental laboratories conducting wastewater surveillance testing, participate in calls and program site visits, as appropriate, and that they budget for travel for two laboratory scientists to attend the NWSS annual meeting.

43. Coordinate and partner to optimize national wastewater surveillance.

  a. Develop or enhance partnerships that will support data collection and reporting to NWSS

    - APHL recommends that public health and environmental laboratories engaged in wastewater surveillance develop and maintain relationships with public health, wastewater treatment facilities, academic and commercial partners to optimize the collection and generation of quality laboratory data to inform public health decisions.

  b. Participate in the NWSS Public Health Community of Practice

    - CDC hosts a health department Community of Practice (CoP). APHL encourages laboratories to participate in this meeting to the extent practical. APHL convenes a Wastewater Surveillance Laboratory CoP, in which all public health and environmental laboratories in NWSS should participate.

  c. Participate in consultations with other health departments/jurisdictions

    - APHL strongly supports the systems approach to NWSS and encourages laboratory participation related to technology, testing and peer-to-peer exchange of ideas.

44. Surveillance data management

  a. Coordinate data management, recordkeeping and reporting for wastewater testing to produce reliable, actionable, and high-quality data for public health action. Implement wastewater sampling strategies and protocols for submission of data to the health department and CDC.

    - APHL recommends coordination and collaboration with other NWSS laboratories and programs to benefit from successful approaches. APHL is developing guidance for laboratories that will aid in determining appropriate workflows, ensuring quality measurements and aims to harmonize measurements across NWSS laboratories.

    - APHL recommends a standardized process for sample accessioning using available technology (i.e., bar codes, QR codes, remote order entry etc.) to improve efficiency and minimize transcription errors. A secure data management system should be developed in collaboration with health department and informatics partners. Defined protocols for data review and reporting should be established and verified prior to use.
b. Submit wastewater from one or more wastewater system to the NWSS DCIPHER portal at least weekly

- APHL recommends development of detailed protocols and timelines in collaboration with partners, to ensure meeting or exceeding project requirements. APHL also recommends the development of a continuity of operations plan (COOP) to provide for critical testing during emergencies and a redundant reporting system to ensure critical data are sent to CDC.

c. Facilitate data sharing among partners to support completeness and timeliness of surveillance data collected and submitted

- APHL recommends working collaboratively with partners to ensure the quality of the laboratory data used for public health decision-making and sharing information, as appropriate.

45. Surveillance data analysis

a. Review and interpret wastewater surveillance data to inform epidemiological and programmatic decisions related to SARS CoV-2 infection.

- APHL recommends working collaboratively with partners to ensure the quality of the laboratory data used for public health decision-making and sharing information, as appropriate.

b. Disseminate data to key stakeholders

Same as a. above

46. Enhance laboratory capacity for wastewater testing

a. Participate in the NWSS Laboratory Community of Practice

APHL convenes the NWSS Laboratory CoP monthly. Email eh@aphl.org to be added to the distribution and to access the electronic messaging platform, CoLABborate.

b. Support laboratory capacity to safely receive, process and test wastewater samples.

- Public health and environmental laboratories should assess their staffing requirements and budget for sufficient qualified scientists and support staff to accomplish programmatic goals.
- APHL also strongly recommends that laboratories include travel costs for scientists to attend the annual NWSS meeting, technical trainings and wastewater surveillance conferences to stay current on methodological advances.
- Sampling & transport Wastewater treatment facilities (WWTF) are important partners for identifying appropriate sampling sites and in the collection of wastewater and/or sludge for testing.
• NWSS programs should consider supporting these important partners to ensure the safe collection and transport of samples to the testing laboratory.
• APHL encourages public health and environmental laboratories to work with WWTFs and health departments to develop sampling and transport protocols.
• Consider materials required for proper transport and storage of samples, such as coolers, consumable materials, cold packs, thermometers and laboratory refrigerators (4C).
• Consider reliable and safe methods of transport in all seasons and weather conditions.
• Sample processing & testing: Multiple testing methods and workflows are used to quantify SARS CoV-2 in wastewater, across the United States. All must be performed in a biological safety level 2 (BSL-2) environment with unidirectional airflow and BSL-3 precautions including respiratory protection and a designated area to don and doff personal protective equipment.
• Consider the required general laboratory safety, biosafety and waste disposal requirements for your laboratory, including but not limited to: engineering controls and space modifications (biological safety cabinets, physical barriers, mobile benches) personal protective equipment (gloves, glasses, shields, respiratory protection, disposable lab coats/coverings) waste disposal (sharps containers, biohazard containment materials, autoclave supplies.
• Consider equipment and supplies for processing wastewater samples (will vary by method/workflow )
  o Storage - laboratory refrigeration at 4 degrees C
  o Sample homogenization (i.e., sonicators, mixers, bead bashers) Sample clarification (i.e., filtration systems, centrifuges)
  o Sample concentration (i.e., ultrafiltration, electronegative filtration, ultracentrifugation and wet chemical techniques - polyethylene (PEG) precipitation and skim milk flocculation)
  o RNA Extraction - extraction kits specific to your workflow. Laboratory controls (matrix control, human fecal normalization, quantitative measurement controls, inhibition assessment and negative controls).
    Consider instrumentation and reagents needed to detect and measure SARS CoV-2 N SARS-CoV-2 may be measured in wastewater by either: RT-qPCR (reverse transcripase, quantitative polymerase chain reaction), or RT-ddPCR (RT-droplet digital PCR) primers and probes (N1 and N2 gene targets, published by CDC and E genes (Corman et al, 2020, EuroSurveillance) accessory or ancillary equipment.
• Consider instrumentation and reagents needed to detect and measure SARS CoV-2 N SARS-CoV-2 may be measured in wastewater by either: RT-qPCR (reverse transcripase, quantitative polymerase chain reaction), or RT-ddPCR (RT-droplet digital PCR) primers and probes (N1 and N2 gene targets, published by CDC and E genes (Corman et al, 2020, EuroSurveillance) accessory or ancillary equipment.
• APHL recommends instrument preventative maintenance and service contracts for all critical instrumentation.
• Evaluate integration information management system (LIMs) with NWSS DCIPHER portal to facilitate streamlined reporting.

• APHL recommends collaboration with health department and informatics partners to assess instrument interface to the facility LIMS and from the LIMS to the DCIPHER portal.


• 59 awards; average of $560,000 per award, total availability of funds: $33,000,000

• Section G1 primarily includes epidemiology and antibiotic stewardship activities. Public health laboratories should contribute to the application and anticipate playing a key role in developing plans to advance the detection, response and containment of AR, maintaining contact and conducting outreach to clinical laboratories and recruiting clinical laboratories to participate in AR Lab Network activities. However, support for laboratory activities should be requested under G2.

Attachment G2: Antibiotic Resistance Laboratory Network (AR Lab Network) (p. 91-106)

**Tier 1**: 55 awards; average of $90,000 per award, total availability of funds: $5,000,000

• All activities under Tier 1 are required for all applicants. PHLs should apply and include request for personnel, reagents, supplies and equipment to support sustaining or enhancing laboratory capacity. It is recommended to separate supply lines by test type when building budgets. Public health laboratories should consider staffing needs to support testing activities as well as outreach and coordination activities (G2/I/Strategy 2a and 3). All testing should be implemented in accordance with current Clinical and Laboratory Standards Institute (CLSI) and in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations.

• **Required testing activities include:**
  - Organism identification, antibiotic susceptibility testing (AST), carbapenemase production testing and carbapenem-resistance mechanism testing for carbapenem-resistant Enterobacterales (CRE) and Pseudomonas aeruginosa (CRPA) isolates.
  
  - Laboratories should ensure that proper technical and human resources are available to support the implementation and continued maintenance of HL7 messaging to CDC using the Data for Action on Antibiotic Resistance Threats (DAART) platform.
  - Targeted technical assistance will be available from APHL to support data exchange goals, however the laboratories will responsible for all LIMS related work as well as building, testing and correcting HL7 message structure and content.

**Tier 2**:

• All PHLs should consider applying for Tier II activities, all of which are optional; laboratories applying for Tier 2 activities must apply for Tier 1 activities. Include requests for personnel, reagents, supplies and equipment. It is recommended to separate supply lines by test type when building budgets.
Strategy 5a: up to 20 awards, average of $5,000 per award, total availability of funds: $100,000

- Laboratories can apply for funds to increase or sustain capacity to conduct reference identification of Candida spp.

- Priority should be given to:
  - All confirmed or suspected Candida auris from anybody site (invasive or non-invasive, sterile or non-sterile)
    - Common misidentifications by identification methods, such as Candida haemulonii on Vitek 2 YST or Candida catenulate by BD Phoenix yeast identification system, should be taken into consideration. These common misidentifications should prompt further work up to rule out C. auris.
  - Candida species other than Candida albicans from any specimen source, especially invasive sites
  - Yeast isolates from any specimen source when unable to identify species after identification was attempted

Strategy 5b: up to 2 awards, average of $175,000-$350,000 per award, total availability of funds: $350,000

- Non-regional laboratories can apply for funds to increase laboratory capacity to perform C. auris colonization screening testing; priority may be given to laboratories in high burden geographic areas. All testing should be implemented in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. The only acceptable laboratory testing methods are:
  - CDC’s defined fungal culture
    - Incubation in an enrichment broth (Salt Sabouraud Dulcitol Broth with Chloramphenicol and Gentamicin) followed by plating and species identification of growth with matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) mass spectrometry.
  - Real-time PCR
    - Prioritized method

- Laboratories should consider staffing needs to support coordination activities at the regional and state or local level and with submitting healthcare facilities.

Strategy 5c: 7 awards, average of $50,000 per award, total availability of funds: $350,000

- Non-regional laboratories can apply for funds to perform WGS to support AR Lab Network priorities and epidemiologic investigations in their jurisdiction.

Priority pathogens include:

- Carbapenemase-producing/PCR-negative isolates confirmed at the Regional Laboratories
- Carbapenem-resistant Acinetobacter baumanii (CRAB) carrying Class A and/or Class B carbapenemase genes
- Carbapenemase-producing/carbapenemase-gene positive CRPA
- Carbapenemase-producing/carbapenemase-gene positive CRE
- Other CRAB with clinically or epidemiologically significant profiles such as
  - resistant to all beta-lactams tested
  - resistant to all carbapenems, but not all beta-lactams tested
o positive for other Class D carbapenemase genes that are NOT common in the submitting jurisdiction

**Tier 3:** 7 awards, average of $2,350,000 per award, total availability of funds: $16,500,000

- CDC previously selected seven PHLs to serve as regional labs. Existing AR Lab Network regional laboratories that are reapplying should consider including requests for funds required to maintain existing services as well as provide enhanced testing or other services. It is recommended to separate supply lines by test type when building budgets.

- The ELC FOA Guidance outlines both required and optional strategies and their associated activities that candidate AR Lab Network regional laboratories may apply for in Strategies 6-12 (p. 97-103). Please note that all activities except those under Strategy 11 below are required. Applying to be the National TB Molecular Surveillance Center (Strategy 12) is optional, but all related activities are required.

- In addition to all activities under Tier 1, laboratories should describe the techniques they will use to collect and test swabs and clinical specimens of:
  - Carbapenem-resistant Acinetobacter baumanii
  - Candida species; for budget development, applicants should anticipate characterizing 1000 to 2000 Candida spp. isolates annually.
  - Highly resistant bacteria via the Expanded Drug Antimicrobial Susceptibility (ExAST) Program; for budget development, applicants should anticipate testing up to 150 isolates annually
  - HAI/AR pathogens via whole genome sequencing; lab should demonstrate sequencing capacity for CROs and Candida spp.

  - Regional laboratories should describe the collaborative activities with state HAI/AR prevention programs to conduct colonization screenings of AR pathogens. This should take into account:
    - Collaboration with the regional epidemiologist for recruitment and coordination of sample submission
    - Regional burden of CROs and C. auris; regions with outbreaks should consider requesting additional funds
    - Communication and workflow protocols allowing for direct transportation of samples to the regional lab

- **Tier III Informatics Activities:**
  - Review APHL ELC guidance language included under Attachment C: Health Information Systems Capacity for general Informatics guidance and additional information that are applicable to these activities.
  - Laboratories should ensure that proper technical and human resources are available to support the implementation and continued maintenance of HL7 messaging to CDC using the Data for Action on Antibiotic Resistance Threats (DAART) platform.
  - Targeted technical assistance will be available from APHL to support data exchange goals, however the laboratories will responsible for all LIMS related work as well as building, testing and correcting HL7 message structure and content.
Regional Laboratories should assign an informatics lead to create, validate, maintain and enhance HL7 data reporting feeds for AR pathogens.

Ensure resources are available for monitoring and troubleshooting AR data exchange flows.

Consider requesting ELC funds to create outreach and communication materials to ensure providers submit necessary or minimum data with specimens so that PHLs can meet CDC reporting requirements.

Consider funding to ensure ongoing LIMS administration to facilitate data ingestion, storage and export capabilities.

Regional laboratories should ensure that informatics staff are available to work with APHL to adopt the Lab Web Portal ETOR solution if they do not already have an ETOR platform they can expand to support AR specific needs. using LIMS Connect. Special consideration should be given to any security assessments needed to utilize this and the installation and testing of the LIMS Connect service at the PHL to support the full functionality of Lab Web Portal (LWP). APHL will provide technical assistance and support to all regional labs who choose to use LWP and LIMS Connect.

*Lab Web Portal (LWP) is a web-based ETOR portal solution deployed on the APHL Informatics Messaging Services (AIMS) Platform that supports electronic test orders and results between PHLs and their submitters.*

If applicable: Ensure resources are available to support onboarding, access management and help desk for users of the Lab Web Portal ETOR system.

If applicable: Consider requesting funding to host informational sessions/trainings for stakeholders using LWP for ARLN test orders and results. This activity will be important as APHL releases new functionality in LWP to support ARLN specific needs. New features will support enhanced lab/epi communication and support laboratory workload scheduling. APHL will provide LWP manuals, guidance, and will support PHLs as adoption of the tool expands.

**Optional Regional Laboratory Testing (G2/Strategies 11-12)**

**Strategy 11:** Regional laboratories can request funds to implement or maintain additional laboratory capacity for the following AR pathogens.

**Strategy 11a:** Azole-resistant Aspergillus fumigatus (up to 300 isolates annually)
- Perform confirmatory species identification
- Testing for azole resistance using the agar plating method. Confirmatory testing must employ broth microdilution following the protocol outlined in CLSI document M38ed3. Custom panels produced by TREK must be used for MIC testing (Catalog # CML3FCAN).

**Strategy 11b:** N. gonorrhoeae surveillance
- AST on up to 5,000 isolates per laboratory annually; preference given to laboratories with proficiency in agar dilution and beta-lactamase testing. Testing must be completed
and non-alert results communicated to submitters within 3 weeks of submission (or as directed).

- WGS for up to 1,750 isolates per laboratory annually; selection of isolates for sequencing will be based on CDC provided criteria.

**Strategy 11c: N. gonorrhoeae reference laboratory capacity-Clinically Reportable (up to 100 samples annually)**

- Isolate N. gonorrhoeae from genital and extra-genital specimens collected from persons with suspected treatment failure
- Perform Etest for azithromycin, ceftriaxone, cefixime and report clinical results to submitters with a 7-10 day turnaround time
- Provide specimen collection and/or transport media

**Strategy 11d: This activity is not going to be funded in BP3; therefore, there is no need to address this activity in the workplan.**

**Strategy 11e: MDR-Streptococcus pneumonia**

**Strategy 11f: Clostridium difficile**

**Strategy 12: Total availability of funds: $1,800,000**

- Laboratories applying to be the National TB Molecular Surveillance Center should request funds to accommodate personnel needs as well as supplies, reagents and storage needs when developing your proposals. Only minor equipment costs (<$10,000/ piece of equipment) can be included in the budget. For budget development, applicants should consider use of a NextSeq Mid-Output Kit with 96 samples per run for prospective WGS. The following activities are required:
  - **Mtb 24 locus MIRU-VNTR typing for approximately 9,000 isolates annually**
  - **Whole genome sequencing via the NextSeq sequencer her for approximately 9,000 isolates annually**
  - **Maintaining a Mtb sample inventory storage system**

**Attachment H: Vector-borne Diseases (p. 107-115)**

- 60 awards, average of $233,000 per award, total availability of funds: $14,000,000
- 5-7 jurisdictions may be awarded $500,000 - $750,000 to support Tier 3 activities

- **A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans has been published here.**

**Tier 1**

- Laboratories should request funding staff typically supported under this activity to maintain basic testing capacity for endemic vector-borne diseases significant to their jurisdiction. At least 0.5 FTE is recommended.
- Laboratories should request funds for reagents to provide molecular and serologic testing for at least one vector-borne disease but are encouraged to maintain testing for more vector-borne diseases. Request funding for equipment (including service/maintenance), consumables and reagents not provided by CDC.
• Laboratories should participate in annual proficiency testing for vector-borne disease diagnostic testing.

• Consider requesting funds to support travel for a laboratorian to attend Vector Week tentatively scheduled for February 2022 in Ft. Collins, CO.

**Tier 2**

• Laboratories applying for tier 2 activities should plan to maintain broader capacity to detect and respond to vector-borne diseases including multiple pathogens both endemic and exotic. Request staff

**Tier 3**

• Laboratories applying to serve as tier 3 laboratories should plan to provide basic (e.g. PCR and IgM serology) and advanced (e.g. MIAs, PRNT, vector) testing for vector-borne disease both viral and bacterial of significance to their jurisdiction either because they are endemic or there is a threat of local transmission. Developing services and capacity to serve as a regional reference center may be considered.

---

### Section III: Disease-Specific Projects

**Attachment I: Mycotics: Detection and Preventing Fungal Infections (p. 116-121)**

- ~30 awards; average of $5,000-$25,000 per award, total availability of funds: $750,000

- Consider including funds for travel to the CDC Mycotic Diseases Branch Mold Identification Course.

- Hologic plans to discontinue Accuprobe products that identify dipmorph fungi (see table below). Consider implementing new protocols for identification molds and fungi including methods such as MALDI-ToF mass spectrometry to identify pathogenic molds and dimorphic fungi as well as testing for endemic mycoses.

<table>
<thead>
<tr>
<th>Hologic Products Identified for End of Life</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Accuprobe, B. dermatitidis Kit</em></td>
<td>102890</td>
</tr>
<tr>
<td><em>Accuprobe, C. immitis Kit</em></td>
<td>102895</td>
</tr>
<tr>
<td><em>Accuprobe, H. capsulatum Kit</em></td>
<td>102910</td>
</tr>
<tr>
<td><em>Accuprobe, L. monocytogenes</em></td>
<td>102920</td>
</tr>
</tbody>
</table>

- Consider requesting funds to facilitate submissions from clinical laboratories to support antifungal-susceptibility testing of *A. fumigatus* at AR Lab Network regional laboratories (Maryland and Tennessee) or at CDC.

- For laboratories in jurisdictions with ongoing transmission of *Candida auris*, consider acquiring laboratory equipment or supplies to support *C. auris* colonization testing.

- Laboratory requests should not duplicate requests made under AR Lab Network activities.
Attachment M: Rabies Surveillance (p. 142-143)

- 10 awards; average of $15,000 per award, total availability of funds: $150,000
  - Priority should be given to maintain staff qualifications and proficiency; recommendations can be found in the national standard protocol.
  - Maintaining proficiency includes travel for attendance at national training course if they have not attended within the last 6 years. Timing of future in-person training activities is uncertain at this time but APHL recommends requesting funds in anticipation of travel resuming.
  - The Wisconsin State Lab of Hygiene Proficiency Testing (PT) program provides rabies PT. Current pricing is available here.
  - Ensure equipment used in DFA is up to date. Consider upgrading fluorescence microscopes. The quality of fluorescence microscopes is critical to the sensitivity of the DFA assay. The national standard protocol contains a discussion on choosing an adequate microscope in Appendix 3.
  - Consider requesting funds to develop, improve or maintain capacity to perform molecular typing of rabies virus variants

Informatics:
- Review APHL ELC guidance language included under Attachment C: Health Information Systems Capacity for general Informatics guidance and additional information that are applicable to these activities.
  - Prepare for enhanced Rabies data exchange initiatives funded through APHL Informatics cooperative agreement*:
    - Consider requesting funds to deploy a new or upgrade/expand an existing animal Rabies LIMS module.
    - Complete mapping of Animal Rabies LIMS data to the HL7 2.5.1 Animal Rabies Message Mapping Template
  - APHL and CDC leads will prioritize and directly contact laboratories to support Rabies data exchange efforts. This initiative will utilize standards-based data exchange, utilizing AIMS services to send Rabies laboratory data to the CDC Rabies program, replacing current reporting mechanisms.

Attachment N: Parasitic Disease Surveillance (p. 144-146)

- 16 awards; average of $5,000 per award, total availability of funds: $80,000
  - Applicants are required to participate in CDC-sponsored diagnostic parasitology workshops or other equivalent trainings. Consider requesting funding to travel to training either at CDC or another public health laboratory. Note that Evaluation Measure #3 focuses on your percentage of proficient laboratorians relative to the workload in your jurisdiction.
• Funding may be requested for expanded surveillance and control of soil-transmitted helminth infections in former endemic areas where transmission may persist (AL, GA, KY, LA, MS, NC, SC and TN) or where on-going transmission is identified. Consider the laboratory costs of providing diagnostic testing to support such efforts.

Attachment O: Enhanced Surveillance of Vaccine-Preventable (VPD) and Respiratory Diseases (p. 147-161)

- 60 awards; average of $123,000 per award, total availability of funds: $7,400,000

- Most jurisdictions do not receive laboratory specific ELC funding for VPDs. However, APHL suggests coordinating with your epidemiology or immunizations partners to ensure that adequate testing services are in place to meet your jurisdictional surveillance needs. In order to improve efficiencies and offer a broader range of testing services some services are available through shared service models. The VPD RCs improve efficiencies and provide a broad range of testing services, offering surveillance testing services for 7 VPDs, including measles, mumps, rubella, varicella-zoster, B. pertussis, H. influenzae, and N. meningitidis. In addition, testing for S. pneumoniae is available through the Antibiotic Resistance Laboratory Network. A subset of viral specimens and all bacterial specimens/isolates tested at the RCs are sent to CDC for additional testing. Results of all VPD testing performed at the RCs are provided to the submitting laboratory via paper report and to CDC via HL7 messaging. If you are interested in learning more about the Reference Centers please contact Kelly Wroblewski (Kelly.wroblewski@aphl.org).

Attachment P – Legionnaires’ Disease Prevention (p. 162-168)

- 30 awards; average of $30,000 - $150,000 per award, total availability of funds: $2,000,000

- APHL recommends submitting proposals that will improve surveillance and testing capacity for Legionella spp.. Suggested activities include developing or maintaining proficiency and expertise in Legionella culture, PCR and WGS methods as well as increasing the number of lower respiratory specimens submitted to PHLs.

- For PCR specifically, note that there are several LDT protocols publically available. Labs are encouraged to propose expenses (e.g., validation testing expenses and consumables) related to the onboarding of a PCR methods to detect Legionella in clinical specimens and/or isolates.

- If a lab is seeking to become ELITE certified, they may want to consider budgeting for culture supplies and consumables in support of this effort.

Attachment Q– Influenza Surveillance and Diagnostic Testing (p. 169-174)

- Traditional influenza surveillance activities: 57 awards; average of $145,614 per award, total availability of funds: $8,300,000

- Enhanced influenza surveillance activities: 15 awards; average of $51,333 per award, availability of funds: $770,000

- For required activities, APHL strongly suggests that you that you place a high priority on personnel. At a minimum, be sure to include staff that was funded on ELC last year. Laboratories should also consider budgeting for service contracts on their ABI 7500 Fast DX instruments. As most reagents and many consumables used for influenza testing are provided by the Influenza Reagent Resource (IRR), those budget items are not likely to be funded.
For optional activities, laboratories should budget for one-time expenses related to achieving the goals set forth in Strategy 1c (aka Tier 2 activities). This may include items such as laboratory and specimen collection supplies or funding for LIMS enhancements to meet the data requirements. Again, these should be one-time expenses; health departments that were previously funded in support of integrating these enhanced surveillance activities through CSTE should not budget for the same items previously funded.

Please review APHL ELC guidance language included under Attachment C: Health Information Systems Capacity for general informatics guidance and additional information about the APHL technical assistance program.

In Attachment C, consider funding to upgrade and enhance PHLIP messaging including:
- Migrate PHLIP reporting to the current HL7 2.5.1 message standard
- Capture ILINet provider information and other epidemiologically important information in LIMS, and add to PHLIP message.

APHL Technical Assistance is available to assist with message upgrades, enhancements, and data transport efforts. For more information about technical assistance or for access to the PHLIP encoding guidelines, please email the Informatics Help Desk at informatics.support@aphl.org.

Attachment R – Non-Influenza Respiratory Diseases: Diagnostics, Reporting and Surveillance (p. 175-178)

- 10-20 awards; average of $55,000 per award, total availability of funds: $750,000

Consider requesting funds for the maintenance, implementation or expansion of non-influenza respiratory virus tests including reagents and personnel. Proposals focused on strengthening surveillance capacity for non-influenza respiratory viruses through PCR and multiplex panels are likely to be given priority as well as assays to type RSV, adeno- and/or enteroviruses strains of public health importance linked to severe outbreaks or severe outcomes. CDC protocols are available upon request.

- See the APHL Respiratory Pathogens page under ID Member Resources for select protocols and lists of commercially available respiratory virus panels. Note that access to the webpage is restricted to APHL members.

Consider budgeting for reporting of non-influenza respiratory pathogen laboratory results to CDC programs including NREVSS, NESS and NATRS. If your laboratory performs typing of adeno and/or enteroviruses, APHL strongly encourages you propose reporting subtype/genotype results to NESS and/or NATRS. For NREVSS reporting, reporting non-influenza respiratory virus surveillance data automatically through PHLIP can replace manual reporting to the National Respiratory and Enteric Virus Surveillance System. As noted, the APHL Informatics Technical Assistance Team may be available to assist staff with updating and validating ELSM implementations. For more information about technical assistance for PHLIP, email informatics.support@aphl.org. See Attachment C: Health Information System for additional Informatics related guidance.
Attachment S: Strengthening the United States Response to Resistant Gonorrhea (p. 179-195)

- Component 1 (Strategies 1-5): Up to 8 awards; average of $650,000 per award, total availability of funds: $6,000,000
- Component 2 (Strategy 6): 4-5 awards, average of $150,000 per award

- All public health laboratories are eligible to apply. Competitive applications will be those that can demonstrate a strong track-record and existing capacity to address the activities listed in the NOFO.
- Public health laboratories should collaborate with your jurisdictional STD prevention and surveillance programs to determine if you plan to apply. Public health laboratories should contribute to applications by describing current capability and capacity to perform gonorrhea culture and susceptibility testing, ability or willingness to validate additional specimen types (particularly self-collected specimens in a non-clinical testing), methods, or approaches as well as any current collaborations with clinical laboratories and providers, current data collection, reporting and storage mechanisms and strategies for expanding capacity if necessary.

- Component 1:
  - Strategy 1:
    - Perform N. gonorrhoeae culture
    - Perform Etest and specimen collection and molecular assay validation activities.
    - PHL should provide laboratory processes for GC culture, AST, and reporting of results; be able rapidly communicate Etest™ results to surveillance and field epidemiology staff;
    - Participate in the development of an AR-GC Outbreak response plan including how they would contribute to enhanced surveillance needs and establish infrastructure, protocols and approaches to access culture-based testing/AST for potential treatment failures
    - Serve as a state-wide center of excellence
      - provide educational materials and webinars on:
        - AR-GC
        - proper sample collection for GC culture
        - development and provision of GC-related lab training, webinars, and SOPs to local public health and hospital laboratories,
        - provide AST for suspected treatment failure
        - provide guidance/support for development of AR-GC outbreak response plans in local jurisdictions, and provision of surge staff support for AR-GC outbreaks.
  - Strategy 2:
    - If applying, PHL will need to ensure self-collected vaginal specimens for GC culture are validated.
  - Strategy 3:
    - This strategy requires that the program encourage all patients with a gonococcal strain identified as having reduced ceftriaxone or cefixime susceptibility to return to the health care facility for a test of cure using NAAT and culture ≥7 days after initial treatment.
Consider how the PHL can support this recommendation.

- **Strategy 4:**
  - Perform GC Culture
  - Perform Etest for ceftriaxone and cefixime as a clinical test with clinically reportable results with rapid communication of results
    - could include LIMS enhancements and use of ETOR
  - Validate a CDC developed molecular assay for detection of cephalosporin resistance
    - CDC will provide protocol and technical support
    - Assay will use remnant specimens that were GC NAAT Positive
    - DNA extraction should be conducted on an automated platform
  - Develop procedures to accept, process and conduct Etest on isolates or specimens for culture collected within the jurisdiction (non-SURRG) for patients with possible treatment failures
  - Ensure validation of additional specimen collection methods and transport, including self-collection in a non-clinical setting and facilitating transport of clinical specimens if program applying for a strategy that includes this approach

- **Strategy 5:** Focused on data management needs regarding reporting results to CDC.

- **Component 2/Strategy 6 (All Optional)**
  Only applicants selected for Component 1 will be awarded a component 2 pilot project.
  - Establish N. gonorrhoeae Test of Cure (TOC) best practices: Looking for piloting of novel models to address the need for test of cure including evaluating of the role of self-collection of specimens in non-clinical settings for specific patient populations. Could implement either NAAT or Culture-based approaches.
  - Establish contact tracing and partner services: No laboratory component
  - Establish GC transport media best practices: Public health laboratory could play a pivotal role in evaluating and improving recovery of N. gonorrhoeae by optimizing aspects of GC transport
  - Develop protocols and enhance local capacity for implementation of culture-independent diagnostic testing and surveillance best practices: This activity is focused on detection of molecular markers of GC drug resistance and/or for evaluation of molecular surveillance.
  - Enhanced AR-GC Laboratory reporting: This activity is focused on reporting of GC AST results from non-PHLs to the health department. Laboratory component minimal to none.
  - Other AR-GC demonstration and evaluation projects: Open to other projects to address critical gaps in US capacity to respond to GC resistance.

Attachment T: Gonococcal Isolate Surveillance Project (GISP) (p.196-210)
- 30 awards; average of $15,000 per award, total availability of funds: $450,000
- Part A: 10 awards, average of $45,000, total availability of funds: $450,000
- Part B: 10 awards, average of $15,000, total availability of funds: $150,000

- Public health laboratories should collaborate with your jurisdictional STD prevention and surveillance programs to determine if you plan to apply. You must apply for the Core GISP surveillance if you wish to apply for eGISP Part A or Part B. If you apply for the Core GISP surveillance you may apply for eGISP Part A, Part B or neither.
- Applicants are requested to provide detailed budgets. For example rather than grouping items into laboratory supplies it is recommended to list out the laboratory supplies that would be
required such as number of plates, swabs and ancillary materials. If applicants are applying for GISP and eGISP consider providing separate budgets for each project (can be placed on the same budget template). Funding can only be used for required GISP and eGISP activities.

- **GISP Core Surveillance**
  Public health laboratories should contribute to applications by describing the following:
  - current capability and capacity to perform gonorrhea culture on non-inhibitory media
  - ability to store and ship isolates to the regional AR-GC laboratory
  - capacity and capability to collect the necessary epidemiological data and manage data, coordinate with other partners.

- **eGISP Part A**
  Applicants should have validated NAAT testing on all specimen types listed below.
  In addition to the requirements for GISP, applicants for eGISP Part A are required to:
  43. perform gram stain on urethral swabs
  44. perform GC culture and subculture isolates onto non-selective media
  45. perform GC NAAT on urethral, pharyngeal, cervical and rectal swab swabs and urine

- **eGISP Part B**
  In addition to the requirements for GISP, applicants for eGISP Part B applicants are required to:
  a. Freeze and maintain all remnant specimens tested by NAAT associated with GISP/eGISP Part A
  b. Ship all remnant specimens associated with GISP/eGISP Part A that corresponded to GC positive cultures to CDC (monthly)

- **Additional Optional Activity:**
  a. Identify and maintain records of all urethral, vaginal/ cervical, and rectal isolates that are suggestive of N. meningitidis (i.e.: positive culture and GC NAAT negative or gram negative intracellular diplococci (GNID) on gramstain and GC NAAT negative)
  b. Ship isolates suggestive of N. meningitidis to CDC (monthly)

**Attachment U: Catalyzing Congenital Syphilis Prevention (CCSP) (p. 211-216):**
- 3-4 awards; average of $93,750 per award, total availability of funds: $375,000

  Activity is focused on programmatic interventions for congenital syphilis. There is not a significant role for public health laboratories-check with your STD prevention and surveillance program if there is any assistance they may need.

**Attachment V: Human Papillomavirus Surveillance Among Men (p. 217-219)**
- 4 (continuing) awards; average of $560,000 per award, total availability of funds: $33,000,000

  If your jurisdictional STD prevention and surveillance program previously participated check in with them to see how the public health laboratory can contribute to this year’s application.
Attachment W: Infants with Congenital Exposure (p. 220-226)

- 30 awards; total availability of funds: $9,492,700
- Jurisdictions can apply under “W” for both Zika infant follow up work and/or other emerging infectious threats — such as Hepatitis C. Ideally, states can utilize existing infrastructure (from Zika or other existing surveillance efforts) and build on that platform for longitudinal mother-baby linked surveillance of HCV.

- Public health laboratories should consider working with their epidemiologists and maternal and child health programs to determine testing needs and strategies and request funds to support laboratory needs for regents and supplies.