



CDC-RFA-OE20 -2001: Enhancing Public Health Laboratory Capabilities and Increasing Capacity

New Focus Area Project Plan Template

SECTION 1: GENERAL INFORMATION

1.	Name of Applicant: Association of Public Health Laboratories (APHL)	2.	Focus Area: Infectious Disease - NCHHSTP
3.	Requested Funding Amount: <i>(Whole Numbers Only)</i> \$500,000	4.	Funding Source (e.g., BA, COVID, PPHF, OPIOID): Base funding - DSTDP
5.	Name of Project: STI Molecular Detection Diagnostics Implementation		
6.	Name of Technical Monitor(s): Ellen Kersh	7.	Technical Monitor(s) Email Address: Egk6@cdc.gov
		8.	Technical Monitor(s) Phone Number: 404.639.2728
9.	Name of Focus Area Coordinator (FAC): Sherry Owen	10.	Email Address of FAC: Smo2@cdc.gov
		11.	Phone Number of FAC: 404.639.1046

SECTION 2: PROJECT SUMMARY

2.1 – Project Description

Project Status: *Select whether your project/activity is an entirely new project or an extension of an existing project:*

- ☒ New CIO Project/Activity
☐ CIO Existing Project/Activity (Expansion/Change of Scope)

Project Description: *Provide a description of the project including a justification for the project's bona fide need in the space below:*

Expanding the development and adoption of molecular detection diagnostic techniques is essential for ensuring the successful identification of STI pathogens. Diagnostics is essential for controlling the spread of STIs, and expansion of molecular assays to characterize these pathogens can improve surveillance efforts for mutations resulting in antibiotic resistant STIs. Although many public health laboratories currently have the ability to conduct STI diagnostics, few labs implement diagnostics to better characterize STI pathogens. This project aims to address this by encouraging greater uptake and development of molecular detection diagnostic methods. Specifically, this project will deploy to support implementation of molecular detection diagnostics for *N. gonorrhoeae* and other STIs caused by pathogens such as *Treponema pallidum*, *Chlamydia trachomatis*, or *Mycoplasma genitalium*. Additionally, this project plans to further evaluate the effectiveness of any currently implemented molecular detection diagnostics methods, while also working to develop new diagnostic techniques that can be used to more effectively diagnose STI infections. This work is necessary because effective laboratory diagnostics allows labs to effectively identify antibiotic resistant strains of STIs. Furthermore, by providing better methods of identifying antibiotic resistant STIs, this project will help address an issue that the CDC has identified as a public health threat.

Activities: Describe activities to be carried out in this project as well as their associated deliverables:

Molecular detection of antibiotic resistance in STIs: This activity will focus on the development and use of molecular detection diagnostic techniques for STIs including *N. gonorrhoeae*, *T. pallidum*, *C. trachomatis*, or *M. genitalium*. This will be accomplished by deploying laboratory developed molecular assays for STI pathogen characterization to public health laboratories to support performance evaluations, multicenter reproducibility evaluations, and to design and develop high quality validation panels for validation of these assays. Additionally, this activity will focus on developing or enhancing culture independent diagnostics tests, especially as it relates to antibiotic resistance. This could allow for the targeted sequencing of STI pathogens to help identify outbreak clusters or detect isolates with concerning antibiotic resistance markers without the delay of needing to recover a culture (or in cases where propagation of the organism is not practical such as for *C. trachomatis* or *T. pallidum*). Deliverables for this activity might include the development of study or implementation designs, increased implementation of molecular detection diagnostic techniques, and a report of evaluation findings and outcomes.

2.2 – Project Strategy and Outcomes

Project Strategies: Select one or more strategies that the project will contribute towards:	☐ S1. Science, Management and Operations ☒ S2. Policy, Partnership and Communication ☒ S3. Training and Capacity Building ☒ S4. Laboratory Quality, Safety and Informatics for Public Health Testing Services, Surveillance and Response
For this Project: Select the outcomes that the project will contribute towards Please check and select responses for all applicable boxes below.	POs and IOs Proposed for this Project
PO-1. Improved collaboration and communication across public health laboratories and other stakeholders.	☒
PO-2. Improved awareness and understanding of public health laboratory capabilities and needs among public health laboratories and other stakeholders.	☐
PO-4. Improved awareness of new tools and resources for public health laboratories and other stakeholders.	☒
PO-5. Increase in needs met due to improved awareness and understanding of public health laboratory training and professional development needs and opportunities among training and workforce development stakeholders.	☐
PO-6. Improved access to and participation in training and workforce development resources and opportunities among current and potential laboratory professionals.	☒
PO-7. Enhanced knowledge, skills, and abilities among current and potential public health laboratory professionals in diverse settings.	☒
PO-8. Improved awareness of public health laboratory informatics capabilities.	☐
PO-9. Improved implementation of quality and safety systems and model practices in public health laboratories.	☐
PO-10. Improved knowledge of technical assistance needs and priorities in state and local public health laboratories.	☐
PO-11. Improved and ongoing awareness and understanding among stakeholders of emerging methods and processes in public health laboratories.	☐
PO-12. Improved dissemination of evidence-based practices to public health laboratories and other stakeholders.	☒
PO-13. Improved laboratory testing capability and surge capacity for emergency response through	☐

equipment procurement, competent staff and partnerships.	
NEW S1.PO-14 Implement approaches to ensure efficiency for committee/subcommittee functions	☐
NEW S1.PO-15 Maintain monitoring and evaluation processes across all focus areas	☐
NEW S1.PO-16 Maintain and ensure process and system of effective knowledge management and commitment to rigorous scientific integrity, quality, and professional standards of practice in development of APHL products	☐
NEW S4.PO-1 Better informatics solutions available for public health laboratory system-wide adoption	☐
NEW S4.PO-2 Improved, timely public health laboratory access to and awareness of needed resources	☐
NEW FLS.C.PO-1 Improved dissemination of clear, compelling, targeted, and timely messages using appropriate communication channels for relevant audiences	☐
NEW FLS.C.PO-2 Increased production of communications materials, websites or other digital platforms, or any other resources with APHL-CDC logo use (i.e., co-branding and logo licensing)	☐
NEW FLS.C.PO-3 Improved dissemination of APHL-CDC co-branded materials or resources for public health laboratories and other stakeholders	☐
NEW Ph2.ID.PO-1 Improve testing capability/capacity to conduct and report low-volume or highly-specialized testing efficiently.	☐
NEW Ph2.PHPR.PO-1 Ensure compliance and access to essential, centralized resources for laboratory testing capability and surge capacity for coordinated emergency response.	☐
NEW QSS-S4.2-PO1. Increased public health laboratory and system partner participation/commitment to L-SIP assessment/reassessment process.	☐
NEW QSS-S4.2-PO3. Improved implementation of quality and safety system model practices across participating public health laboratory system (state/local level).	☐
NEW QSS-S4.2-PO2. Increased participating public health laboratory, system partner knowledge of quality needs and model practices.	☐
IO-1. Expanded Communities of Practice and other collaborative relationships among public health laboratories and other stakeholders.	☐
IO-2. Strengthened information sharing across public health laboratory networks and other stakeholders.	☐
IO-3. Improved engagement and participation of current and potential public health laboratory workforce through application of best practices.	☐
IO-4. Enhanced practices, methods, and infrastructure within the public health laboratory system.	☒
IO-5. Improved data exchange and interoperability among public health laboratories and their partners.	☐
IO-6. Improved public health laboratory detection, surveillance, and response.	☒
IO-7. Improved quality and safety in public health laboratories.	☐
NEW S1.IO-8 Ensured effective leadership and management system for committees/subcommittees	☐
NEW S1.IO-9 An effective monitoring and evaluation system across the organization	☐
NEW S2.IO-3 (Old PO-3) Improved support for public health laboratories among policy makers	☐
NEW S3.IO-1 Leadership development participants granted increased leadership roles and/or responsibilities	☐
NEW S4.IO-1 System-wide adoption of informatics and data management solutions among public health laboratories and their partners	☐
NEW S4.IO-2 Increased use of resources/outputs created and shared via technical assistance responses	☐
NEW S4.IO-3 Improved technical capability among recipients as a result of fulfilled requests	☐
NEW FLS.C.IO-1 Improved reach of clear, compelling, targeted, and timely messages among relevant audiences	☐
NEW FLS.C.IO-2 Enhanced adoption or use of APHL-CDC co-branded materials or resources among public health laboratories and other stakeholders	☐

SECTION 3: PROPOSED BUDGET

Instructions for Use of funds: *Provide any restrictions or instructions for applicant use of funds, as applicable:*

Not applicable.

SECTION 4: ADDITIONAL CONSIDERATIONS

Reviewers' feedback on additional considerations (if any):

Funding for this proposal has not currently been allocated and the source of funding is under discussion. The final amount of available funding may be less than the projection included in this proposal.

2/26/2021

X Ellen N. Kersh

Technical Monitor/Submitter

Signed by: PIV