

Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats

Request for OMB Approval of an Existing Collection in Use without an OMB Control Number

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Supporting Statement A

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- **Goal of the study:** The goal is to establish a network of public health laboratories to improve detection and characterization of urgent antibiotic resistant threats in healthcare-associated infections, carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), carbapenem-resistant *Acinetobacter baumannii* (CRAB), and *Candida* species, including *C. auris*.
- **Intended use of the resulting data:** The results from laboratory testing will be used to (1) identify and contain new and emerging antibiotic resistant threats, including carbapenemase-producing organisms that can spread carbapenem-resistance through mobile genetic elements, (2) describe the geographical distribution of antibiotic resistant threats, (3) detect novel resistance phenotypes and genotypes among healthcare-associated organisms, (4) describe and reduce the spread of resistance mechanisms, and (5) provide data for regional, state, and local infection prevention programs to set priorities and mount targeted containment and prevention responses.
- **Methods to be used to collect:** Participating laboratories will report all testing results to CDC at least monthly using a secure online web-portal, REDCap, or Health Level 7 (HL7) transmission. All testing results that indicate immediate threats to patient safety and require rapid public health action will be communicated to CDC and local public health authorities within one day of identification. Participating labs will also submit an annual report describing current testing methods and an annual performance measurement report.
- **The subpopulation to be studied:** State and local public health laboratories (currently including those of all 50 states, a few large cities, and Puerto Rico). A subset of these jurisdictions also participates in *Candida* spp. identification activities. A small subset of state public health labs (currently seven) also serve as regional labs to provide confirmatory reference testing for jurisdictions within their region.
- **How data will be analyzed:** Data will be analyzed using applicable electronic data analysis

The Centers for Disease Control and Prevention (CDC) is requesting approval of the continued information collection for a 3-year period to support continued monitoring and analysis of isolates and collection methods for antibiotic resistant organisms.

This project was initially designed to be led by only seven state health departments as regional laboratories, thus not requiring OMB clearance. Additional last-minute funding became available for rapid detection of AR as an urgent public health threat. The additional funding allowed for expansion to include all 50 states before OMB clearance could be sought. Building such infrastructure required defining needs and scope and understanding key elements important to the packet submission after first full year of implementation. While packet submission was initiated early in 2019, current guidance indicated that data collection could continue uninterrupted during OMB packet development. CDC is bringing the data collection into compliance now.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Antibiotic resistance has the potential to impact all Americans at every stage of life and CDC is working to drive aggressive action and empower the nation to comprehensively respond to these threats. The

National Action Plan Sub-Objective 2.1.1 describes creation of “a regional public health laboratory network that uses standardized testing platforms to expand the availability of reference testing services”, and facilitation of “rapid data analysis and dissemination of information.” CDC has created this public health laboratory network and named it the Antibiotic Resistance Laboratory Network (AR Lab Network). The mission of the AR Lab Network is to offer gold-standard lab capacity to all state and regional labs to improve detection and laboratory diagnostics, thereby increasing the capacity of state and local health departments for rapid detection and faster response to outbreaks and emerging antibiotic resistance related to healthcare-associated infections. Testing done in the AR Lab Network will enable local detection, characterization, and tracking of an urgent antibiotic resistant threats (<http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>) and improve local epidemiological understanding of these threats.

This state and local public health laboratory testing capacity is being implemented by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in response to the Executive Order 13676 of September 18, 2014 (Attachment 1a), the National Strategy for Combating Antibiotic Resistant Bacteria of September 2014 (Attachment 1b) and to implement sub-objective 2.1.1 of the National Action Plan for Combating Antibiotic Resistant Bacteria of March 2015 (Attachment 1c). Data collected throughout this network is also authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) – (Attachment 1d).

CDC’s AR Lab Network supports nationwide lab capacity to rapidly detect antibiotic resistance and inform local public health responses to prevent spread and protect people. It closes the gap between local laboratory capabilities and the data needed to combat antibiotic resistance by providing comprehensive lab capacity and infrastructure for detecting antibiotic-resistant pathogens (germs), cutting-edge technology, like DNA sequencing, and rapid sharing of actionable data to drive infection control responses and help treat infections. This infrastructure allows the public health community to rapidly detect emerging antibiotic-resistant threats in healthcare, food, and the community, mount a comprehensive local response, and better understand these deadly threats to quickly contain them.

One component of the AR Lab Network is testing conducted by jurisdictional public health laboratories (currently including those of all fifty states, a few large cities, and Puerto Rico). These laboratories will be equipped to detect and characterize carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB) isolates and detect carbapenemase producing organisms (CPOs) from screening swabs. Characterization of these resistant bacteria, which are typically identified in clinical laboratories, is often limited despite the fact they are becoming more prevalent, particularly in healthcare settings. The proposed laboratory testing will allow for additional testing and characterization, including use of gold-standard methods. Isolate characterization includes organism identification, antimicrobial susceptibility testing (AST) to confirm carbapenem resistance and determine susceptibility to new drugs of therapeutic and epidemiological importance, a phenotypic method to detect carbapenemase enzyme production, and molecular testing to identify the resistance mechanism(s). Screening swabs will undergo molecular testing to identify carbapenemase genes present. Results from this laboratory testing will be used to (1) identify targets for infection control, (2) detect new types of resistance, (3) characterize geographical distribution of resistance, (4) determine whether resistance mechanisms are spreading among organisms, people, and facilities, and (5) provide data that informs state and local public health surveillance and prevention activities and priorities.

Additionally, a subset of jurisdictions will participate in reference identification of *Candida* spp. to aid in these pursuits using matrix-assisted laser desorption ionization/time-of-flight (MALDI-TOF) mass spectrometry or deoxyribonucleic acid (DNA) based sequencing.

2. Purpose and Use of Information Collection

The purpose of this information collection is to (1) provide data that informs patient safety and infection control, (2) detect new types of resistance as well as emerging fungal threats, including those with resistance, (3) characterize geographical distribution of resistance, (4) determine whether resistance mechanisms are spreading among organisms, people, and facilities, and (5) provide data that informs state and local public health surveillance and prevention activities and priorities.

Isolates with targeted resistance characteristics, suspected *Candida* isolates, and swabs taken from patients at high risk for targeted resistance are shipped from clinical laboratories and facilities to public health laboratories in the AR Lab Network. Results from public health laboratory testing will be reported back to the submitters, to public health infection prevention programs, and to CDC. Healthcare facilities will use the testing results to understand infection control targets and priorities in their facility. State and local infection prevention programs will use the data to identify where and when prevention efforts are most needed. CDC will use the information to better understand antibiotic resistance in healthcare-associated infections, improve domestic capacity to detect and respond to emerging resistance mechanisms and resistant organisms, enhance antibiotic stewardship efforts, and develop a national strategy for prevention of antibiotic resistant threats.

Use of information collected: funded state and local public health laboratories will provide the following information to the Program Office at CDC - Division of Healthcare Quality Promotion (DHQP):

1. Annually, participating laboratories will submit a report summarizing testing methods and volume (Attachment 3a: Summary of Testing Methods). These reports will be submitted by email to ARLN_DHQP@cdc.gov. These measures are to be used by the Program Office (DHQP) to determine the ability of each laboratory to confirm and characterize targeted AR organisms and their overall capacity to support state healthcare-associated infection (HAI)/AR prevention programs.
2. Annually, participating laboratories will provide an Evaluation and Performance Measurement Report (Attachment 3b) to CDC via email to HAIAR@cdc.gov. Data will be used to indicate progress made toward program objectives and challenges encountered.
3. Participating laboratories will report all testing results to CDC (Attachment 3c), at least monthly, by CSV or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to (1) provide data for state and local infection prevention programs, (2) identify new types of antibiotic resistant organisms, (3) identify new resistance mechanisms in targeted organisms, (4) describe the spread of targeted resistance mechanisms, and (5) identify geographical distribution of antibiotic resistance or other epidemiological trends. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC, submitting facilities and clinical laboratories. For messaging to CDC, these messaging protocols will be based in Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform. The AIMS platform is a secure environment that provides shared services to assist public health laboratories in the transport, validation and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time,

allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.

4. For those resistant organisms and mechanisms that pose an immediate threat to patient safety and require rapid infection control, facility assessments, and/or additional diagnostics, an immediate communication to the local healthcare-associated infection program in the jurisdictional public health department and CDC is needed. The “AR Lab Network Alerts” encompass targeted AR threats that include new and rare plasmid-mediated (“jumping”) carbapenemase genes, isolates resistant to all drugs tested, and detection of human reservoirs for transmission. These alerts must be sent within one working day of detection. Participating laboratories will utilize REDCap to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date (Attachment 3d: ARLN Alert Report Form).

Sites participating in *Candida* identification testing will also provide the following to the Mycotics Program Office at CDC - Division of Foodborne, Waterborne, and Environmental Diseases (DFWED):

1. Annually, participating laboratories will provide an Evaluation and Performance Measurement Report (Attachment 3e) to CDC via email to ARLN@cdc.gov. Data will be used to indicate progress made toward program objectives and challenges encountered.
2. Participating laboratories will report all testing results to CDC (Attachment 3f), requested at least monthly, by REDCap or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to (1) identify and track antifungal resistance and emerging fungal pathogens, and (2) aid public health departments and healthcare facilities in rapidly responding to fungal public health threats and outbreaks. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC, submitting facilities and clinical laboratories. For messaging to CDC, these messaging protocols will be based in REDCap or the AIMS platform. The REDCap and AIMS platforms are secure environments that provide shared services to assist public health laboratories in the transport, validation and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time, allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.
3. For those resistant organisms that pose an immediate threat to patient safety and require rapid infection control, facility assessments, and/or additional diagnostics, an immediate communication to the local healthcare-associated infection program in the jurisdictional public health department and CDC is needed. The “AR Lab Network Alerts” encompass targeted AR threats that include *C. auris*, which is rapidly emerging in healthcare settings. These alerts must be sent within one working day of detection. Participating laboratories will utilize REDCap and/or email to ARLN_alert@cdc.gov to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date (Attachment 3g: AR Lab Network Alert Report Form for *C. auris*).

3. Use of Improved Information Technology and Burden Reduction

CDC collects the minimum information necessary for the purposes of maintaining the AR Lab Network and ensuring that data are actionable. Information collected are stored in Public Health Laboratory Information Management systems (LIMS), data is entered when isolates are tested, and data is reported to CDC either through a CSV upload electronically to APHL AIMS Reporting portal or email to AR Lab Network. Use of existing LIMS allows for reduce burden of data management. AIMS is beginning the transition to use of HL7 messaging technology to further enhance information technology and reduce burden on public health laboratories. As a stopgap to allow transmission of data while AIMS and public health LIMS systems are updated, REDCap is used. REDCap is a no-cost, secure platform which allows for real-time data transmission, management, and visualization for public health laboratories and CDC.

4. Efforts to Identify Duplication and Use of Similar Information

Carbapenem-resistant Enterobacteriaceae have been recognized by the Centers for Disease Control and Prevention as an urgent public health threat, while multidrug-resistant *Acinetobacter* and *Pseudomonas*, and fluconazole-resistant *Candida* have been identified as serious public health threats (<http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>). Some states require reporting of CRE, CRPA, and/or CRAB (summarized in Attachment 4). These infections are not nationally notifiable conditions; consequently, there is no requirement to report these infections to CDC. CP-CRE and clinical *C. auris* cases were made nationally notifiable in 2018 (for transmission to CDC through the Nationally Notifiable Disease Surveillance System, or NNDSS). This, in turn, has resulted in more states making *C. auris* (summarized in Attachment 6), CP-CRE, or CRE reportable. In many states, isolate submission to the public health laboratory is required or requested.

Presently, CDC collects partial information on CRE from two surveillance systems: The Emerging Infections Program (EIP) Multi-site resistant Gram-negative Surveillance Initiative (MuGSI) (0920-0852) (<https://www.cdc.gov/hai/eip/mugsi.html>), and the National Healthcare Safety Network (NHSN) (<http://www.cdc.gov/nhsn/about-nhsn/index.html>). CDC collects even less information on CRPA and CRAB. MuGSI does not collect data on CRPA, and collects only patient data for CRAB, no isolate data. Additionally, NHSN collects limited data on CRPA and CRAB (0920-0666). Similarly, CDC collects limited information on *Candida* from EIP (<https://www.cdc.gov/hai/eip/candida.html>) and NHSN.

Although CRE, CRPA, and CRAB infection data are collected from some sources, the data are not sufficient for tracking these types of infections in all 50 states and do not provide detailed isolate-level information on antimicrobial susceptibilities, carbapenemase production, mechanisms of resistance, changes in geographical distribution across the United States, organism identification across numerous CRE genera, or transmission of resistance from one organism to others (including from one type of CRE to another, or between CRE and other pathogens like *Pseudomonas aeruginosa* and *Acinetobacter baumannii*). These data are important to detect new resistance mechanisms that cause infections that require new drugs and to discover epidemiological trends that require new infection prevention strategies.

Current data collection is also limited for *Candida* spp. Many of the existing data focus on bloodstream *Candida*, although *Candida* can be isolated from several different body sites and drug resistance often develops in sites like, urine, where penetration for some drugs is low. For *C. auris*, patients are considered at risk for transmission regardless of colonized or infected body site, and only about 50% of clinical cases are found in the blood. Most critically, though, fungal laboratory capacity is low in many areas of the country, resulting in a lack of data and potential delays in public health action. Public health

laboratories may only perform minimal fungal species identification tests or may only use basic laboratory testing methods, which cannot accurately detect species of concern, like *C. auris*. Equipping jurisdictional laboratories to perform accurate in-house *Candida* testing on a range of specimen sources allows for faster, actionable results and more comprehensive monitoring for emerging and resistant species.

Combating resistant pathogens requires early detection of new resistance, new trends and geographical distribution so that robust prevention efforts can be initiated. The laboratory testing conducted by the AR Lab Network fills data gaps and complements data collected through EIP, NHSN, and NNDSS. Specifically, the AR Lab Network will test isolates and screening swabs from all 50 states, whereas EIP tests a subset of isolates from defined catchment areas in 10 states. EIP surveillance is population-based and focuses on special research studies that cannot practically be implemented using the AR Lab Network while the AR Lab Network focuses on rapid detection and characterization of novel and emerging resistance threats. Finally, the new AR Lab Network establishes nationwide isolate collection and characterization capacity, whereas NHSN reporting is limited to healthcare facility-generated reports of infections and susceptibility data.

Participating public health laboratories will provide information about new types of carbapenem-resistance, emerging fungal and bacterial pathogens, and new and emerging resistance mechanisms, provide data to contain and prevent the spread of these resistant infections across the US, and help identify new trends in antibiotic resistance epidemiology. The AR Lab Network testing capacity will be linked to CDC-funded public health department prevention programs (<https://www.cdc.gov/drugresistance/pdf/state-ar-prevention-protect-programs.pdf>).

5. Impact on Small Businesses or Other Small Entities

No small business or other small entities are involved in this data collection. Respondents submitting reports to CDC are state or local governmental public health laboratories. The data requested has been held to the absolute minimum required for its proposed use. CDC recommends that AR isolates should be collected from acute care hospitals and long-term care facilities, where resistance can be a problem. Participation in AR Lab Network specimen submission is voluntary, unless mandated by state or jurisdictional reporting and isolate submission bylaws. Healthcare facilities and clinical laboratories will send clinical specimens to their jurisdictional public health laboratories under guidance of, and in coordination with, their state's public health authorities. All expenses for shipping of resistant specimens to AR Lab Network public health laboratories may be charged to a FedEx account provided by CDC.

6. Consequences of Collecting the Information Less Frequently

Monthly testing reports and annual testing process reports from AR Lab Network labs are required in order to use data for rapid public health response and to ensure that program outcomes are being met and accurate and up-to-date laboratory methods are validated and in use.

Knowledge of historical antimicrobial resistance data indicates that resistance patterns and threats can change rapidly; therefore, participating laboratories report testing data on a monthly basis to the Program Offices of the Division of Healthcare Quality Promotion and the Mycotic Diseases Branch at CDC. This timeliness will ensure adequate detection and reporting of trends in antimicrobial resistance at state, regional, and national levels. The data generated by AR Lab Network labs needs to be submitted

on a regular monthly basis for detection of new or unusual resistance, for finding changes in epidemiological trends and for coordinated responses to an antimicrobial resistance infection event that may involve multiple localities or regions.

For urgent AR threats that may be spread easily from organism to organism, person to person, and facility to facility, rapid communication (“ARLN alerts”) to coordinating healthcare-associated infection programs in the local health department and CDC is needed to facilitate rapid responses to contain and prevent additional spread. Many health departments still rely on CDC assistance with supplemental laboratory testing (i.e., whole genome sequencing) and/or infection control consultations and facility assessments.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Participating laboratories report on a monthly basis targeted carbapenem-resistant organism testing results to the Division of Healthcare Quality Promotion (DHQP) Program at CDC; the Mycotic Diseases Branch at CDC also requests monthly data submissions. In addition, participating laboratories are required to report immediate alerts to CDC (DHQP) for any novel and/or unusual antimicrobial resistance in targeted organisms with anticipated elevated public health consequences. New or unusual antimicrobial resistance could be caused by unknown mechanisms of resistance. An isolate may have a new or unusual resistance mechanism if carbapenemase production is detected but molecular tests are negative for known carbapenemase genes. Questionable samples may be rare but could be detected by a laboratory on any testing day. Consequently, the frequency of submitting test results to CDC may exceed a monthly requirement. In general, if there is a possibility of a public health emergency and shorter turnaround timeframes are necessary to limit the severity and spread of resistant infections, communication will be established to encourage faster responses.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60-day Federal Register Notice was published in the Federal Register on 07/05/2019 (Vol. 84, No. 129, page 32182-32184 (Attachment 2)). One comment was received from the public (Attachment 2a).
- B. AR laboratory testing and reporting conducted by state and local public health laboratories is a collaborative project among CDC and funded jurisdictional public health laboratories located around the United States. Frequent consultations between CDC and persons outside CDC are anticipated. These consultations may involve such topics as the availability of data, clarity of instructions, and data elements to be recorded and may take place via: 1) site visits to participating laboratories; 2) regular meetings of subject matter experts who are associated with the participating laboratories and clinics; and 3) e-mail communications among all personnel participating in project activities. The Association of Public Health Laboratories (APHL) is one of the CDC’s essential sources of input for the State Laboratory Testing, in particular on the subject of data messaging capabilities and applicability of APHL Messaging Services (AIMS) Platform, interoperability of data transport protocols, and long-term public health information exchange model. In addition, CDC experts will be interacting with other experts in health sciences, medicine, and public health as well as consumers, patient advocates, and diagnostic equipment manufacturers.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The ID Enterprise LIMS – Interoperability HL7 Messaging (ID ELIMS HL7) system is a data repository for multiple data collection efforts at CDC. ID ELIMS HL7 does contain Personally Identifiable Information, however no individually identifiable information will be included in this data collection. The information obtained will be recorded in such a manner that subjects cannot be identified directly or through specimen identifiers. No identifying information, such as names, birthdays and addresses, will be recorded in the data sets. The ID numbers that link to identifying information will not be included in the data file submitted to CDC. Therefore, data collection will have little to no effect on patients' privacy. All electronic data will be stored on secured CDC servers and will be accessible only by designated CDC staff directly involved in the project.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

Under [45 CFR 46](#), '*Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters)*' are not deemed to be research and therefore do not require IRB or Human Subject Approval. The AR Lab Network activity falls into this category, and therefore requires no further action for IRB approval.

Justification for Sensitive Questions

This data collection effort does not include any personally invasive or sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The estimated annualized burden hours were determined as follows. There are up to 55 laboratories within this framework. A "respondent" refers to a single participating public health laboratory. A "response" is defined as the data collection/processing associated with an individual specimen from an individual patient.

CDC recommends that specimens be tested from clinical labs serving acute care hospitals at a minimum. If possible, isolate collection should be extended to cover labs serving other healthcare facility types where resistance can be a problem (e.g., long-term care facilities). The number of isolates collected by a public health laboratory will depend upon the prevalence of resistance in the jurisdiction, its reporting and isolate submission laws for the targeted organisms, and the volume capabilities of the jurisdictional public health laboratory.

In low prevalence areas, it is recommended that all available CRE, CRPA, and CRAB isolates occurring in the area be tested at the jurisdictional public health lab. In higher prevalence areas a sampling strategy focused on high-risk facilities and/or populations, guided by the jurisdictional public health department's healthcare-associated infection program, should be engaged. Screening swabs from patient contacts should be collected and tested in accordance with CDC recommendations to identify potential transmission.

The average burden per response for the Annual Summary of Testing Methods (Attachment 3a) was evaluated to be 0.1 hours.

The average burden per response for the bacterial and fungal Annual Evaluation and Performance Measurement Reports (Attachments 3b and 3e) were evaluated to be 4 hours and 2 hours, respectively.

Based on previous laboratory experience in analyzing carbapenem-resistant isolates and specimens, the estimated time for each participating laboratory for Monthly Data Report (Attachment 3c) is 4 hours per response. Because of the need to add more data collection points as new drugs are developed, new susceptibility testing methods are made available, new resistance mechanisms emerge, and new pathogens are prioritized as threats, the Monthly Data Report (Attachment 3c) includes some placeholder elements in expectation of evolving needs. For *Candida* identification, elements to include are minimal (specimen ID, submitting laboratory ID, etc.) and the estimated time for each participating laboratory for the *Candida* Monthly Data Report (Attachment 3f) is 2 hours.

The use of ARLN Alerts (Attachment 3d) encompass targeted AR threats that include new and rare plasmid-mediated ("jumping") carbapenemase genes, isolates that are non-susceptible to all drugs tested, and detection of novel resistance mechanisms. These alerts must be sent within one working day of detection. The elements of these messages include the unique public health laboratory specimen ID and a summary of specimen testing results generated to date. With the conversion to HL7 messaging of these data will be transmitted in real-time, thus eliminating the need to send alerts. Until that time, REDCap will be utilized to communicate alerts. CDC estimates that public health laboratories send an average of 34 ARLN Alerts per lab each year, with an estimated burden per response of 0.1 hours. The estimated burden of response for *Candida* identification is also 0.1 hours, though far fewer alerts are reported yearly (estimated to be approximately 700 total per year including all 55 jurisdictions, averaging to 13 per each jurisdiction).

The total estimated annualized burden across all AR Lab Network labs and activities for DHQP and DFWED combined is 4555 hours, though this is likely an overestimation since it is possible only a portion of the 55 jurisdictions will participate in *Candida* identification testing. Public Health laboratories receive federal funds through CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) mechanism to participate in this project. There are no additional costs to respondents other than their time.

Table A.12: Estimated Annualized Burden Hours

Type of Respondents	Form name	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Public Health Laboratories	Annual Report of Bacterial Specimen Testing Methods	55	1	6/60	6
Public Health Laboratories	Annual Evaluation and Performance Measurement Report for Bacterial Specimen Testing	55	1	4	220
Public Health Laboratories	Monthly Testing Results Reports—Bacterial Specimen Testing	55	12	4	2640
Public Health Laboratories	AR Lab Network Alerts—Bacterial Specimen Testing	55	34	6/60	187
Public Health Laboratories	Annual Evaluation and Performance Measurement Report (<i>Candida</i> identification)	55	1	2	110
Public Health Laboratories	Monthly Testing Results Reports – <i>Candida</i> identification	55	12	2	1,320

Public Health Laboratories	AR Lab Network Alerts – <i>Candida auris</i>	55	13	6/60	72
Total					4,555

B. Estimated Annualized Burden Costs

Estimated hourly rates are based on OPM 2019 salary tables for the locality pay for the rest of U.S. (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/RUS_h.pdf). For the AR Lab Network public health laboratories, the rate will be based on a GS 7 Step 1 2019 Schedule with a 1.4% general and 15.37% locality percent at \$19.82/hour.

Table B.12: Estimated Annualized Costs (for both bacterial and fungal activities)

Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Public Health Laboratory Staff	4555	\$19.82	\$90,280.10

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

14. Annualized Cost to the Government

State and local CRE/CRPA/CRAB laboratory capacity and *Candida* identification is supported by the CDC’s Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) funding instrument, with up to 55 awards (Attachment 5; “G2, Tiers 1 and 2”, page 142). Total costs to the Federal Government are referenced in the Table A.14.

Table A.14: Estimated Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Health Scientist (GS-14, 1.0 FTE)	\$103,106.00

	CDC Health Scientist (GS-11, 0.15 FTE)	\$9,817.00
	CDC Medical Officer (GP-13, 0.05 FTE)	\$7,355.00
	CDC Laboratory Personnel (GS-14, .20 FTE)	\$20,621.20
	CDC Laboratory Personnel (GS-13, .20 FTE)	\$17,450.40
	CDC Laboratory Personnel (GS-13, .20 FTE)	\$17,450.40
	CDC Laboratory Personnel (GS-11, .50 FTE)	\$30,609.00
	CDC Laboratory Personnel (GS-9, .50 FTE)	\$25,299.00
	CDC Laboratory Personnel (GS-9, .50 FTE)	\$25,299.00
	CDC Data Manager (GS-13, .5 FTE)	\$43,626.00
	CDC Project Coordinator (GS-12, 1.0 FTE)	\$73,375.00
	Subtotal, Direct Costs to the Government	\$374,008.00
Travel and other related expenses	Travel (7 sites annually), supplies, equipment, service contracts	\$141,000.00
	Subtotal, Travel and other project-related expenses	\$141,000.00
Federal Grant (awards)	Healthcare-Associated Infection/Antimicrobial Resistance Activities State CRE/CRPA Laboratory Capacity G2 (Attachment 5, "G2")	\$6,000,000
	Subtotal, Federal Grant	\$6,000,000
	TOTAL COST TO THE GOVERNMENT	\$6,515,008.00

15. Explanation for Program Changes or Adjustments

None.

16. Plans for Tabulation and Publication and Project Time Schedule

To make public health laboratory testing data widely available, CDC will publish finalized data in annual reports and peer-reviewed manuscripts. CDC will also share data routinely with contributing

public health labs and departments and add AR Lab Network data to the new DHQP Patient Safety Portal (formerly the Patient Safety Atlas) for easy public access, download, and visualization. There are no immediate plans for a similar strategy for *Candida* identification.

Reports of overall resistance trends and novel findings will involve CDC staff. Papers and presentations describing analyses of data from an outbreak investigation or a specific jurisdiction(s) should involve staff from the relevant site. Local use of data to support state and local HAI/AR prevention programs is encouraged and supported. Sites can develop manuscripts for peer-reviewed publication based on local results data. In all cases, investigators should acknowledge AR Lab Network testing as the source of data in the methods section. Additional reporting of any bacterial specimen testing conducted in partnership with regional laboratories will be shared widely via annual reports and published on DHQP's Patient Safety Portal.

This is a recurring data collection. A 3-year OMB clearance is requested.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

1. The Authorizing Legislation
 - a. Presidential Executive Order 13676 of September 18
 - b. The National Strategy for Combating Antibiotic Resistant Bacteria (September 2014)
 - c. The National Action Plan for Combating Antibiotic Resistant Bacteria (March 2015)
 - d. Public Health Service Act (42 USC 241) Section 301
2. 60 Day Federal Register Notice
 - a. Public Comment
3. Data Collection Forms
 - a. Form 1 - Annual Report of Bacterial Specimen Testing Methods
 - b. Form 2 - Annual Evaluation and Performance Measurement Report for Bacterial Specimen Testing
 - c. Form 3 - Monthly Data Report Form for Bacterial Specimen Testing
 - d. Form 4 – AR Laboratory Network Alert Report Form for Bacterial Specimen Testing
 - e. Form 5 – Annual Evaluation and Performance Measurement Report (*Candida* identification)
 - f. Form 6 – Monthly Data Report Form – *Candida* identification
 - g. Form 7 – AR Lab Network Alert Form for *Candida auris*
4. Summary of CRE/CRPA/CRAB reporting by states
5. ELC ARLN State Testing Activities
6. Summary of *Candida* reporting by states
7. Human Subjects Exemption (Umbrella Protocol Number 7218)