Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats

Revision of a Currently Approved Collection

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Supporting Statement A

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- The goal is to establish a network of public health laboratories to improve detection and characterization of urgent antimicrobial resistant threats such as carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), carbapenem-resistant *Acinetobacter baumannii* (CRAB), *Candida* species, including *C. auris*, and *Neisseria gonorrhoeae.*
- The results from laboratory testing will be used to (1) identify and contain new and emerging antimicrobial resistant threats, (2) describe the geographical distribution of antimicrobial resistant threats, (3) detect novel resistance phenotypes and genotypes among antimicrobial resistant threats, (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 use to collect data: 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.
- Participants: State and local public health laboratories (currently including those of all 50 states, a few large cities, counties, Guam, and Puerto Rico). All laboratories participate in core testing which includes testing for carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), carbapenem-resistant *Acinetobacter baumannii* (CRAB), *and Candida auris* identification. A subset of laboratories conducts *Neisseria gonorrhoeae* testing and colonization screening testing for pathogens that are traditionally healthcare-associated (e.g., CRE, CRAB, and *C. auris*).
- A small subset of state public health labs (currently seven) also serves as regional labs to provide confirmatory reference testing for jurisdictions within their region.
- Data will be analyzed using applicable electronic data analysis tools.

CDC is requesting a 3-year approval for revisions made to "Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats" (OMB Control No. 0920-1310) which supports the data collected through the Antimicrobial Resistance Laboratory Network (AR Lab Network). A revision is being submitted to 1) add new data elements to the data collection forms, 2) to ensure that the burden of generating electronic messages for data transmission are accounted for, and 3) to accommodate changes to the Performance Measures (PMs) used to monitor the performance of the AR Lab Network.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Antimicrobial resistance has the potential to impact all Americans at every stage of life and the Centers for Disease Control and Prevention (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." The CDC has created this public health laboratory network and named it the Antimicrobial Resistance Laboratory Network (AR Lab Network). The mission of the AR Lab Network is to offer validated high-quality laboratory testing through funding support of state and regional labs so these labs can build the capacity and the capability to locally improve detection and

laboratory diagnostics. Through building strength nationally through public health laboratories this thereby increases the capacity of state and local health departments for rapid detection and faster response to outbreaks and emerging antimicrobial resistance among bacterial and fungal pathogens (https://www.cdc.gov/antimicrobial-resistance/media/pdfs/2019-ar-threats-report-508.pdf).

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 of September 2014 (Attachment 1b) and to implement the National Action Plan of October 2020 for Combating Antibiotic-Resistant Bacteria (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).

The CDC's AR Lab Network closes the gap between local laboratory capabilities and the data needed to combat antimicrobial resistance by providing comprehensive lab capacity and infrastructure for detecting antimicrobial-resistant pathogens (germs), advanced 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 antimicrobial-resistant threats in healthcare, food, and the community, mount a comprehensive local response, and better understand these deadly threats to quickly contain them.

The AR Lab Network is a network of jurisdictional public health laboratories currently including those of all fifty states, the District of Columbia, Los Angeles County, Houston, New York City, Philadelphia, Guam, and Puerto Rico. Laboratories are financially supported through the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative agreement (CDC-RFA-CK-24-0002; Search Results Detail | Grants.gov) to perform testing, support workforce, and laboratory infrastructure.

The AR Lab Network is divided into Tiers. Jurisdictional public health laboratories fall into a Tier based on the testing that they perform (see Table A.1). All laboratories within the Network participate in Tier 1 activities. In addition, some laboratories participate in Tier 2 or 3 activities .

Laboratory activities supported through the AR Lab Network's three Tiers fall into the following categories:

1) Core testing, support for important antimicrobial resistant pathogens that are traditionally healthcare-associated, including carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), carbapenem-resistant *Acinetobacter baumannii* (CRAB), *Candida* species, including *C. auris*, (all Tiers)
2) Jurisdictional testing capacity that supports *Neisseria gonorrhoeae* surveillance (Tier 2 and 3),
3) Testing of colonization screening samples to support local public health response (Tier 2 and 3), and
4) Enhanced testing capacity at the regional laboratories (currently seven Regional Labs, Tier 3).

Table A.1 Listing of the testing methodologies offered by AR Lab Network by laboratory Tier

Laboratory Tier	Laboratory Testing	Estimated Number of Laboratories
Tier 1	Detection and identification of traditionally the healthcare-associated organisms, carbapenemase-producing organisms	57

	(CPOs) (i.e., CRE, CRAB, CRPA) and Candida species. Confirmatory antimicrobial susceptibility testing (AST) and resistance mechanism testing for CRE, CRAB, and CRPA.	
Tier 2	Antifungal susceptibility testing for Candida isolates and whole genome sequencing (WGS) for *Candida auris*.	4
	Candida auris colonization screening through ELC Program I.	5
	Antimicrobial susceptibility testing using gradient strip methodology (i.e., Etest) *Neisseria gonorrhoeae* through the SHARP project[1].	17
	Colonization screening for traditionally healthcare-associated organisms including carbapenemase-producing organisms (CPOs) (i.e., CRE, CRAB, CRPA) and *Candida auris* through the SHARP project[1].	31
	WGS for Carbapenemase-Producing Organisms through the SHARP project[1].	40
Tier 3 (i.e., Regional Labs) 7	Expanded Antimicrobial Susceptibility Testing (ExAST) of traditionally healthcare-associated bacteria (e.g., CRE, CRAB, CRPA).	7
	WGS for Carbapenemase-producing organisms.	7
	Detection of azole-resistant *Aspergillus fumigatus.*	2
	Antimicrobial susceptibility testing using traditional methodology or gradient strips (i.e., Etest) and WGS for *Neisseria gonorrhoeae* isolates collected through surveillance.	4
	Antimicrobial susceptibility testing and serotyping of *Streptococcus pneumoniae.*	2
	Special projects focused on *Clostridioides difficile*.	1
	Detection of antimicrobial-resistant dermatophytes.	1
	Antimicrobial susceptibility testing for *Haemophilus influenzae*.	1
	Characterization of *Mycoplasma genitalium (*Mgen*)* isolates collected through surveillance.	0
	WGS of isolates of *Mycobacterium tuberculosis* (Mtb).	1
	Colonization screening for traditionally healthcare-associated organisms including carbapenemase-producing organisms (CPOs) (i.e., CRE, CRAB, CRPA) and *Candida auris.*	7
	Detection, antimicrobial susceptibility testing, genetic mechanisms testing and WGS of traditionally healthcare-associated bacteria on specimens collected from companion animals.	2
	Detection traditionally healthcare-associated organisms from wastewater samples collected from long-term care facilities through surveillance.	0

[1] The Strengthening HAI/AR Program Capacity (SHARP) project is a supplemental funding award under the ELC Cooperative Agreement.

2. Purpose and Use of Information Collection

Purpose: to (1) provide data that informs patient safety and infection control, (2) detect new and emerging resistance among traditionally healthcare-associated pathogens, (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.

To support these aims, the AR Lab Network collects data that falls into the following two categories 1) performance measurement/evaluation data, and 2) data about isolate testing. Testing data that are shared with the CDC for the purpose of this network arrive in several formats- using REDCap reports, CSV uploads and through the use of HL7. Work that is reported in REDCap requires the use of data collection instruments included in this package. The burden for building the HL7 messages for the purpose of sharing testing data to CDC is also included in this package.

Performance measurement/evaluation information that is collected by CDC is used in the following ways:

- The Program Office at CDC - Division of Healthcare Quality Promotion (DHQP) collects information about traditionally healthcare-associated bacterial pathogens, which include carbapenemase-producing organisms (CPOs) (i.e., CRE, CRAB, CRPA). Annually, participating laboratories will report on a set of Evaluation and Performance Measures (PMs) (Attachments 2a, 2b, 2d, 2f, 2q, 2s, 2t). Data will be entered into a data management platform that our ELC Partnering Office will determine (e.g., REDCap or CAMP). Data will be used to indicate progress made towards program objectives and challenges encountered. The performance measure data that are collected is generated in labs all three of the Tiers.
- The Mycotics Program Office at CDC - Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) collects information about traditionally healthcare-associated fungal pathogens; e.g., *Candida* spps. Annually, participating laboratories will report on a set of Evaluation and Performance Measures (PMs) (Attachments 2b, 2c, 2e, 2p, 2l). Data will be entered into a data management platform that our ELC Partnering Office will determine (e.g., REDCap or Cooperative Agreement Management Platform [CAMP]). Data will be used to indicate progress made towards program objectives and challenges encountered. The performance measurement data that are collected is generated labs in all three of the Tiers.
- The Sexually Transmitted Disease (STD) Laboratory Reference and Research Branch (SLRRB) at CDC - Division of STD Prevention (DSTDP) collects information on the detection and characterization *Neisseria gonorrhoeae*. Annually, participating laboratories will provide an Evaluation and Performance Measure Report (Attachments 2h,2i, 2t, and 2u). Data will be used to indicate progress made toward program objectives and challenges encountered. The performance measurement data that are collected is generated in Tier 2 and 3 labs.
- The Antimicrobial Resistance Coordination and Strategy Unit (ARX), at CDC, collects performance measures data from the following Tier 3/Regional Laboratories: 2g, 2j, 2k, 2m, 2n, 2o, 2q, 2r. Data will be used to indicate progress made toward program objectives and challenges encountered. ARX also collects performance measure 2s. This measure is collected across all three laboratory Tiers.

Data that is collected by CDC from testing performed in by the AR Lab Network is used in the following ways.

- State and local public health laboratories, that perform testing, will provide the following information to the Program Office at CDC - Division of Healthcare Quality Promotion (DHQP) about traditionally healthcare-associated bacterial pathogens, which include carbapenemase-producing organisms (CPOs) (i.e., CRE, CRAB, CRPA). This work is performed across all three Tiers:

    - Annually, participating laboratories will submit a report summarizing testing methods and volume (Attachment 3a). These reports will be submitted via REDCap. These measures are to be used by the Program Office (DHQP) to determine the ability of each laboratory to confirm and characterize carbapenemase-producing organisms and their overall capacity to support state healthcare-associated infection (HAI)/AR prevention programs.

    - Participating laboratories will report all testing results to CDC (Attachment 3b), 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 antimicrobial resistant organisms, (3) identify new resistance mechanisms in targeted organisms, (4) describe the spread of targeted resistance mechanisms, and (5) identify geographical distribution of antimicrobial 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.

    - 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 for CPOs" serve this purpose of providing a platform of communicating important laboratory generated results with "those who need to know". 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 3c).

- State and local public health laboratories, that perform testing, will provide the following information to the Mycotics Program Office at CDC - Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) about traditionally healthcare-associated fungal pathogens; e.g., *Candida* spps. This work is performed across all three Tiers:

    - Participating laboratories will report all *Candida* spp. testing results (e.g., organism identification, antifungal susceptibility testing, whole genome sequencing [WGS], colonization screening) to CDC (Attachments 3d and 3e), 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, (2) aid public health departments and healthcare facilities in rapidly responding to fungal public health threats and outbreaks, (3) support outbreak investigations (i.e., helping to identify new introductions and ongoing or undetected transmission), and (4) to monitor circulating clades and strains. 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 (in case of HL7). 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.

- 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 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).

- Regional laboratories that perform testing for *Aspergillus fumigatus* report data to CDC using real-time HL7 transmission. This testing is provided as a service for clinicians since antifungal susceptibility testing for this pathogen is not widely available in the United States. Data collected are used to inform what is known about resistance in the United States. Although azole-resistant *A. fumigatus* currently appears to be uncommon in the United States, resistance has been increasingly detected in Europe and is associated with worse outcomes compared with azole-sensitive *A. fumigatus;* thus, ongoing monitoring in the United States remains a public health priority.

- State and local public health laboratories, that perform testing, will provide the following information to the Sexually Transmitted Disease (STD) Laboratory Reference and Research Branch (SLRRB) at CDC - Division of STD Prevention (DSTDP) on the detection and characterization *Neisseria gonorrhoeae*. These activities are performed in Tier 2 and 3 laboratories.

    - Participating laboratories will notify CDC DTSDP of any isolate(s) identified to demonstrate an "alert" minimal inhibitory concentration (MIC) as defined by SLRRB within one working day. Laboratories will utilize REDCap or email 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 3f).

- Participating laboratories will report all testing results to CDC (Attachment 3f and 3g), requested at least monthly, by email, REDCap, or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to support 1) national treatment recommendations, 2) local health departments determine distribution and use of STD prevention services and resources, guide prevention planning, and communicate best treatment practices to health care providers, and 3) aid public health departments and healthcare facilities in timely responding to antibiotic resistant gonorrhea. 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 currently supports CSV and HL7 but are working towards full HL7 implementation, allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.

Samples from patients with traditionally healthcare-associated pathogens (e.g., CRE, CRAB, CRPA, *Candida* spp.), community pathogens of concern (e.g., *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*) are shipped from clinical laboratories and healthcare facilities to public health laboratories in the AR Lab Network for testing. 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 testing results, for traditionally healthcare-associated pathogens, to understand infection control targets and priorities in their facility and to better understand the epidemiology of important pathogens. State and local infection prevention programs will use the data to identify where and when prevention efforts are most needed in their jurisdictions.

CDC will use all generated testing information to better understand antimicrobial resistance in healthcare and the community, improve domestic capacity to detect and respond to emerging resistance mechanisms and resistant organisms, enhance antibiotic stewardship efforts, improve vaccine effectiveness, and develop a national strategy for prevention of antimicrobial resistant (AR) threats.

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 samples are tested, and data is reported to CDC either through a CSV upload electronically to APHL AIMS Reporting portal, through HL7 messaging, or through an email to AR Lab Network (i.e., in the case of alert data). Use of existing LIMS allows for reduce burden of data management. AIMS, additionally allows the 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

Some states require reporting of carbapenem-resistant *Enterobacteriaceae* (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), carbapenem-resistant *Acinetobacter baumannii* (CRAB) (Attachment 5) and/or *Candida* spp., including *C. auris* (Attachment 7), and *N. gonorrhoeae*. State and local CRE/CRPA/CRAB/*Candida*/*N. gonorrhoeae* laboratory capacity is supported by the CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) funding instrument, with up to 57 awards (Attachment 6, "ELC ARLN State Testing Activities", page 145).

Carbapenem-resistant Enterobacteriaceae and *Acinetobacter*, drug-resistant *Neisseria gonorrhoeae*, and *Candida auris* have been recognized by the Centers for Disease Control and Prevention as an urgent public health threat, while multidrug-resistant *Pseudomonas*, drug-resistant *Streptococcus pneumoniae* and drug-resistant *Candida* species *(*non- *C. auris)* have been identified as serious public health threats. Both azole-resistant *Aspergillus fumigatus* and drug-resistant *Bordetella pertussis* have been added to CDC's watch list. (Antibiotic Resistance Threats in the United States, 2019 (cdc.gov). Carbapenemase-producing organisms (CPOs)(e.g., CRE and CRAB) and clinical *C. auris* cases were made nationally notifiable in 2022 (for transmission to CDC through the Nationally Notifiable Disease Surveillance System, or NNDSS, OMB Control Number 0920-0728). In many states, isolate submission to the public health laboratory is required or requested.

Presently, CDC collects partial information on CRE, and CRAB from two surveillance systems: The Emerging Infections Program (EIP) Multi-site resistant Gram-negative Surveillance Initiative (MuGSI) (OMB Control Number 0920-0978) (https://www.cdc.gov/hai/eip/mugsi.html), and the National Healthcare Safety Network (NHSN) (http://www.cdc.gov/nhsn/about-nhsn/index.html).. MuGSI does not currently collect data on CRPA; NHSN collects limited data on CRPA and CRAB (OMB Control Number 0920-0666).

Although CRE, CRPA, and CRAB infection data are collected as mentioned, 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. Some *C. auris* data is collected through NNDSS and bloodstream *Candida* data is collected through laboratory- and population-based surveillance from select states as part of the EIP (https://www.cdc.gov/hai/eip/candida.html)(OMB Control Number 0920-0978). However, *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.

The data collected through this project for *Aspergillus fumigatus* is unique, as there are not other federal systems collecting this data in the United States.

Neisseria gonorrhoeae infection is a national notifiable condition, however, associated antimicrobial resistance is not nationally notifiable. CDC conducts sentinel site surveillance for resistance through a large surveillance activity supported through the ELC called Combating Antimicrobial Resistant Gonorrhea and other Sexually Transmitted Infections (CARGOS). Rapid antimicrobial testing of suspected treatment failure cases at the state and local public health lab level is not provided through CARGOS. CARGOS also has limited capacity for detecting outbreaks or importation of resistance unless they occur at the approximately 20 annually selected surveillance sites. The CARGOS program is currently building an OMB/PRA package, however, the data elements that are currently part of this data collection are currently being collected as part of Gonococcal Isolate Surveillance Program (GISP; OMB Control No. 0920-0307) and the United States Response to Resistance Gonorrhea (SURRG; OMB. Control No. 0920-1242). Building capacity for testing in more public health jurisdictions would enable a faster turnaround time for detecting antibiotic resistant *N. gonorrhoeae* and have an impact on patient treatment. With the recent CDC STD treatment guideline change to monotherapy with ceftriaxone, increasing antimicrobial susceptibility testing among the state and local public health labs could help identify emerging cases of antibiotic resistance. Collection of testing data at these labs will enhance awareness of resistance and allow the CDC to engage with the jurisdictions on how to handle these cases.

Laboratory- and population-based surveillance for *S. pneumoniae* and *H. influenzae* is being conducted through the EIP's Active Bacterial Core surveillance program (OMB Control Number 0920-0978). These data support the understanding of the epidemiology of and provided information regarding the serogroups are current circulating nationally. However, over time the EIP catchment area has become less representative, and therefore supporting additional isolate collection and characterization through the AR Lab Network has become necessary to ensure that the vaccine available to combat the spread of these pathogens accurately represent the serogroups causing disease. The data collected on the testing of these isolates is collected through the Public Health Laboratory Interoperability Project (PHLIP), which is a data exchange and interoperability project, and these organisms are only collected at two laboratories, and is therefore not included in this package.

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, CARGOS 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 12 states. EIP surveillance is population-based and focuses on special projects 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 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 testing for 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 antimicrobial 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, long-term care facilities, or in other clinical settings, 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 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, the Mycotic Diseases Branch, and the Division of STD Prevention 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 organisms 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 at a minimum, on monthly basis organism testing results to the Division of Healthcare Quality Promotion (DHQP) Program, the Mycotic Diseases Branch and the Division of STD Prevention at CDC, as described in section A6. In addition, participating laboratories are required

to report immediate alerts to CDC targeted organisms with anticipated elevated public health consequences.

As stated in A6, delays in reporting could result in serious public health consequences. There are no other special circumstances relating to the guidelines of CRF 1320.5.

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 06/17/2024 (Vol. 89, No. 117, page 51345- 51348 (Attachment 4). CDC did not receive public comments related to this notice.
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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act applies and that there are no changes to the Privacy aspects of this package. Privacy Impact Assessment attached (Attachments 9A-C).

Date of birth will be the only individually identifiable information will be collected. 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 and addresses, will be recorded in the data that is shared with the CDC. 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.
Data will be kept private to the extent allowed by law.

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

Institutional Review Board (IRB)

The AR Lab Network has received a non-research determination (Attachment 8).

The current *N. gonorrhoeae* data collection is considered non-research (Attachment 10 and 11). As stated previously in this package, the programs of GISP and SURRG are being combined into one cohesive surveillance program called CARGOS. As this program evolves, the current data collection falls under the SURRG determination included with this package.

Justification for Sensitive Questions
This data collection effort does not include any personally invasive or sensitive questions.

Due to the nature of our data collection methods, the AR Lab Network is reliant on how race and ethnicity is collected by our partnering public health labs, and how these fields are structured in their LIMS systems. CDC does not support the maintenance of these systems. Additionally updating and modifying the HL7 messages that are used for this Network require a change control process. However, despite these barriers, the AR Lab Network is planning to structure our generated HL7 messages to be compliant to the Notice of Decision published in the Federal Register on March 29, 2024 regarding the update of the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), the data collections under this PRA package will comply with the updated standards set for Federal data on Race and Ethnicity by and/or before the March 2029 deadline.

12. Estimates of Annualized Burden Hours and Costs

For this revision, the total estimated burden is 57,872 hours. The previous approval was for an estimated annual burden of 4950 hours.

Table A.12: Estimated Annualized Burden Hours

Attachment	Type of Respondents	Form name	Number of Respondents	Average Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
2a	Public Health Laboratories	I.1 – ROUTINE TESTING BY GENERA IN JURISDICTION- Annual	57	1	10/60	10

		Evaluation and Performance Measurement Report				
2b	Public Health Laboratories	I.2- EXPANDED DRUG SUSCEPTIBILITY TESTING (ExAST) IN JURISDICTION- Annual Evaluation and Performance Measurement Report	7	1	10/60	1
2c	Public Health Laboratories	I.3- CANDIDA SPECIES IDENTIFICATION IN JURISDICTION- Annual Evaluation and Performance Measurement Report	57	1	10/60	10
2d	Public Health Laboratories	I.4- HAIAR WHOLE GENOME SEQUENCING (WGS) OF GRAM-NEGATIVE AR THREATS IN JURISDICTION- Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10
2e	Public Health Laboratories	I.5- C. AURIS COLONIZATION SCREENING IN JURISDICTION-Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10
2f	Public Health Laboratories	I.6- CARBAPENEMASE-PRODUCING ORGANISM (CPO) SCREENING IN JURISDICTION- Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10
2g	Public Health	I.7- AZOLE	2	1	20/60	1

	Laboratories	RESISTANCE IN CLINICAL ASPERGILLUS FUMIGATUS ISOLATES- Annual Evaluation and Performance Measurement Report				
2h	Public Health Laboratories	I.8- N. GONORRHOEAE WHOLE GENOME SEQUENCING (WGS)- Annual Evaluation and Performance Measurement Report	4	1	10/60	1
2i	Public Health Laboratories	I.9- GONOCOCCAL (GC) ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) IN JURISDICTION- Annual Evaluation and Performance Measurement Report	4	1	20/60	1
2j	Public Health Laboratories	I.10- WHOLE GENOME SEQUENCING (WGS) OF S. PNEUMONAIE - Annual Evaluation and Performance Measurement Report	2	1	20/60	1
2k	Public Health Laboratories	I.11- CLOSTRIDIOIDES DIFFICILE (C. DIFFICLE) TESTING IN JURISDICTION- Annual Evaluation and Performance Measurement Report	2	1	20/60	1
2l	Public Health Laboratories	I.12- ANTIFUNGAL RESISTANT TINEA DERMATOPHYTES - Annual Evaluation and Performance Measurement Report	3	1	20/60	1
2m	Public Health	I.13- ANTIMICROBIAL	2	1	20/60	1

	Laboratories	SUSCEPTIBILITY TESTING (AST) OF INVASIVE HAEMOPHILUS INFLUENZAE (H. INFLUENZAE) IN JURISDICTION- Annual Evaluation and Performance Measurement Report				
2n	Public Health Laboratories	I.14- MYCOPLASMA GENTALIUM (MG)- Annual Evaluation and Performance Measurement Report	4	1	20/60	1
2o	Public Health Laboratories	I.15- MOLECULAR Mtb TESTING- Annual Evaluation and Performance Measurement Report	Up to 20	1	10/60	3
2p	Public Health Laboratories	I.16- C. AURIS WHOLE GENOME SEQUENCING (WGS) IN JURISDICTION- Annual Evaluation and Performance Measurement Report	Up to 57	1	10/60	10
2q	Public Health Laboratories	I.17- MONITORIING CRE CRPA IN COMPANION ANIMALS TO FROM HUMANS- Annual Evaluation and Performance Measurement Report	Up to 2	1	20/60	1
2r	Public Health Laboratories	I.18- HEALTHCARE WASTEWATER-BASED SURVEILLANCE - Annual Evaluation and Performance Measurement Report	Up to 2	1	20/60	1
2s	Public Health Laboratories	I.19- COMMUNICATION AND COORDINATION	57	1	10/60	10

		OFACTIONABLE EPI LAB DATA IN JURISDICTION- Annual Evaluation and Performance Measurement Report				
2t	Public Health Laboratories	I.20-CHARACTERIZATION OF THE CLINICAL LABORATORY NETWORK IN JURISDICTION-Annual Evaluation and Performance Measurement Report	57	1	10/60	10
2u	Public Health Laboratories	I.21 NEISSERIA GONORRHOEAE ETEST FOR SHARP	17	1	20/60	6
3a	Public Health Laboratories	AR Lab Network Annual Report of Testing Methods for Carbapenemase-producing Organisms	57	1	2	114
3b	Public Health Laboratories	AR Lab Network Monthly Data Report Form for Carbapenemase-producing Organisms	57	1302	20/60	24,738
3c	Public Health Laboratories	AR Lab Network Alert Report Form for Carbapenemase-producing Organisms	57	214	3/60	610
3d	Public Health Laboratories	AR Lab Network Alert and Monthly Data Report Form for *Candida*	Up to 57	1671	20/60	31,749
3e	Public Health Laboratories	AR Lab Network Form for Phylogenetic Tree-level Mycotics Reporting	Up to 57	30	6/60	171
3f	Public Health Laboratories	AR Lab Network Alert and Monthly Data Report Form for *Neisseria gonorrhoeae*	17	93	6/60	158
3g	Public Health	AR Lab Network DAART	4	50	10/60	33

	Laboratories	data elements for *Neisseria gonorrhoeae*				
NA	Public Health Laboratories	HL7 Messages updates-IT Maintenance	32	4	20/60	43
NA	Public Health Laboratories	Implementation of new HL7 messages—IT Initial Set up	11	4	3	132
NA	Public Health Laboratories	CSV files updates for Carbapenemase-producing organisms-IT Maintenance	24	1	1	24
	Total					57,872

B. Estimated Annualized Burden Costs

Estimated hourly rates are based on the National estimates for Clinical Laboratory Technologists and Technicians, May 2023 table. (Clinical Laboratory Technologists and Technicians (bls.gov). For the AR Lab Network public health laboratories, the rate will be based on the mean hourly wage provided in the 'employment estimates and mean wage estimates'.

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	57,872	$30.22	$1,748,892

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

None.

14. Annualized Cost to the Government

The work described in this package is supported through the CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative agreement under Program I (https://www.grants.gov/search-results-detail/348437). The funding level for the most current budget period is listed below. 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)	$122,198.00
	CDC Health Scientist (GS-11, 0.15 FTE)	$10,882.95
	CDC Medical Officer (GP-13, 0.05 FTE)	$8,471.40
	CDC Laboratory Personnel (GS-14, .20 FTE)	$24,439.60
	CDC Laboratory Personnel (GS-13, .20 FTE)	$20,681.80
	CDC Laboratory Personnel (GS-13, .20 FTE)	$20,681.80
	CDC Laboratory Personnel (GS-11, .50 FTE)	$36,276.50
	CDC Laboratory Personnel (GS-9, .50 FTE)	$29,983.00
	CDC Laboratory Personnel (GS-9, .50 FTE)	$29,983.00
	CDC Data Manager (GS-13, .5 FTE)	$51,704.50
	CDC Project Coordinator (GS-12, 1.0 FTE)	$86,962.00
	Subtotal, Direct Costs to the Government	$442,264.55
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)	ELC Testing Activities for Laboratory Capacity (Attachment 6)	$12,000,000
	Subtotal, Federal Grant	$12,000,000
	TOTAL COST TO THE GOVERNMENT	$12,583,264.55

15. Explanation for Program Changes or Adjustments

A revision is being submitted to 1) add new data elements to the data collection forms, 2) remove outdated data collection forms, 3) to ensure that the burden of generating electronic messages for data transmission are accounted for, and 4) to accommodate changes to the Performance Measures (PMs) used to monitor the performance of the AR Lab Network. The data collection forms have been included because for some testing types up to 57 jurisdictions (i.e., state and local public health laboratories) will be participating (see Table A.1).

There are 21 Performance Measure documents being added to the package. These individual Performance Measure documents replace the existing documents, which consolidated multiple Performance Measures into single documents. In some cases, modifications are also made to the existing individual Performance Measure documents.

We estimate an additional 52,922 burden hours have been added to the package because of the following:

- We have reviewed and updated the time it takes to complete each performance measure.
- We have reviewed the time it takes to complete each data collect form to ensure all burden is accounted for taking into consideration the increases in testing that have occurred.
- We have added the burden for electronic messaging.

Please see Table A.15, a cross walk of the current packages data attachments (i.e., data collection forms) with the prior attachments that were submitted for this Network.

Table A.15: Crosswalk documenting the prior OMB package forms submitted with the current package attachments. The status of attachments is indicated in the Status column.

Current Package Attachment	**Prior Package Attachment**	**Status**	
Performance Measure Attachments			
	Attachment 3b (Form 2)- Annual Evaluation and Performance Measurement Report for Bacterial Specimen Testing	Removed	
	Attachment 3e (Form 5)- Annual evaluation and Performance Measurement Report (Candida)	Removed	
	Attachment 3h (Form 8)- Annual Evaluation	Removed	

	and Performance Measurement Report (*Neisseria gonorrhoeae*) final		
	Attachment 3j (Form 10)-Annual Evaluation and Performance measurement Report (C. auris WGS)	Removed	
Attachment 2a_I.1: Routine testing by genera in jurisdiction – Annual evaluation and performance measurement report Attachment 2b_I.2: Expanded drug susceptibility testing (ExAST) in jurisdiction- Annual evaluation and performance measurement report Attachment 2c_I.3: Candida species identification in jurisdiction – Annual performance measurement report Attachment 2d_I.4: HAIAR whole genome sequencing (WGS) of gram-negative AR threats in jurisdiction – Annual evaluation and performance measurement Attachment 2e_I.5: *C. auris* colonization screening in jurisdictions – Annual evaluation and performance measurement report Attachment 2f_I.6- Carbapenemase-producing organism (CPO) screening in jurisdiction- Annual		New data collections	

evaluation and performance measurement report Attachment 2g_I.7- Azole resistance in clinical Aspergillus fumigatus isolates- Annual evaluation and performance measurement report Attachment 2h_I.8- N. gonorrhoeae whole genome sequencing (WGS)- Annual evaluation and performance measurement report Attachment 2i_ I.9- Gonococcal (GC) antimicrobial susceptibility testing (AST) in jurisdiction- Annual evaluation and performance measurement report Attachment 2j_I.10- Whole genome sequencing (WGS) of S. pneumonaie -Annual evaluation and performance measurement report Attachment 2k_I.11- Clostridioides difficile (C. difficile) testing in jurisdiction- Annual evaluation and performance measurement report Attachment 2l_I.12- Antifungal resistant tinea dermatophytes -Annual evaluation and performance measurement report Attachment 2m_I.13- Antimicrobial susceptibility testing (AST) of invasive Haemophilus influenzae (H. influenzae) in jurisdiction-			

annual evaluation and performance measurement report Attachment 2n_I.14- Mycoplasma gentalium (MG)- Annual evaluation and performance measurement report Attachment 2o_ I.15- Mtb testing- Annual evaluation and performance measurement report Attachment 2p_I.16- C. auris whole genome sequencing (WGS) in jurisdiction- Annual evaluation and performance measurement report Attachment 2q_I.17- Monitoring CRE CRPA in companion animals to from humans-Annual evaluation and performance measurement report Attachment 2r_I.18- Healthcare wastewater-based surveillance - Annual evaluation and performance measurement report Attachment 2s_I.19- Communication and coordination of actionable epi lab data in jurisdiction- Annual evaluation and performance measurement report Attachment 2t_I.20- Characterization of the clinical laboratory network in jurisdiction-Annual evaluation and performance			

measurement report Attachment 2u_I.21 Neisseria gonorrhoeae etest for SHARP			
Carbapenemase-producing Organisms Data Collection Forms (CPOs)			
Attachment 3a- AR Lab Network Annual Report of Testing Methods for Carbapenemase_producing Organisms	Attachment 3a (Form 1)- Annual Report of Bacterial Specimen Testing Methods	Form name changed; data collection unchanged	
Attachment 3b - AR Lab Network Monthly Data Report Form for Carbapenemase-producing Organisms	Attachment 3c (Form 3)- Monthly Data Report Form for Bacterial Specimen Testing	New data collection	
Attachment 3c - AR Lab Network Alert Report Form for Carbapenemase-producing Organisms	Attachment 3d (Form 4)- AR Lab Network Alert Report Form for Bacterial Specimen Testing	Form name changed; data collection unchanged	
Traditionally healthcare-associated fungal pathogens			
Attachment 3d - AR Lab Network Alert and Monthly Data Report Form for Candida		New data collection	
Attachment 3e - AR Lab Network Form for Phylogenetic Tree-level Mycotics Reporting		New data collection	
	Attachment 3f (Form 6)- Monthly Data Report Form Candida	Removed	
	Attachment 3g (Form 7)- AR Lab Network Alert Report Form for C.auris	Removed	
	Attachment 3k (Form	Removed	

	11) - AR Lab Network Alert and Monthly Data Report Form for isolate and Specimen-level Mycotics Testing (C. auris WGS)		
	Attachment 3l (Form 12) - AR Lab Network Alert and Monthly Data Report Form for Phylogentic Tree-level Mycotics Reporting (C. auris WGS)	Removed	
Neisseria gonorrhoeae			
Attachment 3f - AR Lab Network Alert and Monthly Data Report Form for *Neisseria gonorrhoeae*		New data collection	
Attachment 3g - AR Lab Network DAART data elements for *Neisseria gonorrhoeae*		New data collection	
	Attachment 3i (Form 9) - AR Lab Network Alert and Monthly Data Report Form for *Neisseria gonorrhoeae*	Removed	

Summary of changes and justification for the Performance Measures (Attachments 2a – Attachment 2u): For the next 5-year cycle for the ELC Cooperative Agreement, a set of new performance measures have been developed to ensure that funding that is provided to the AR Lab Network laboratories, through ELC, are being used as needed to meet the objectives of the Network. These new performance measures will replace the prior performance measures, and the removed forms are documented in Table A.15. The new measures were created to reflect the new scope of work that is being implemented across all testing capacities during the new 5-year funding cycle of the ELC cooperative agreement. Additionally, performance measures (PMs) are being included in this package, regardless of the number of expected respondents (e.g., some PMs will be completed by 7 or fewer labs, see Table A.12). The collection of the performance measures added a total of 95 burden hours to this package.

Summary of changes and justification for CPO data collection that will be provided to the Program Office of CDC - DHQP (Attachments 3a – 3c): The AR Lab Network has built testing capacity across the nation to rapidly detect CPOs. Additionally, a result of SHARP funding, the AR Lab Network Labs has the capacity to increase the level of testing it can perform. This expansion in infrastructure will result in more testing results and therefore the burden for Attachments 3a-3c has been increased because

of anticipated increased testing. No new data elements were added to Attachment 3a, formerly labeled Annual Report of Bacterial Specimen Testing Methods. Attachment 3b is a new data collection form, replacing the prior data collection form labeled Monthly Data Report Form for Bacterial Specimen Testing. This data collection from has been changed so that data collection is relevant, to the change in the scope of work that will be implemented for the CPO testing activity, during the next 5-year cycle of the ELC cooperative agreement. No new data elements were added to Attachment 3c, formerly labeled AR Lab Network Alert Report Form for Bacterial Specimen Testing. With the expanded increase in the burden of disease, and the introduction of Attachment 3b, for CPOs the total burden hours for these three forms are estimated at 25,462 burden hours.

Summary of changes and justification for data collection on traditionally healthcare-associated fungal pathogens that will be provided to the Program Office of CDC – DFWED (Attachments 3d – 3e): The AR Lab Network has built testing capacity across the nation to rapidly detect important antimicrobial resistant mycotic diseases. Additionally, as result of SHARP funding, the AR Lab Network Labs have the capacity to increase the level of testing these labs can perform. This expansion in infrastructure, and the implementation of the new 5-year cycle of the ELC cooperative agreement's scope of work, will result in different and more testing results and therefore two new forms were needed (Attachment 3d-3e). Additionally, the burden for the data collection for the Mycotic diseases has increased from prior years forms, because of the change in work scope and the anticipated increased testing volume. Four data collection forms have been removed as documented in Table A.15. These forms were removed as the data collection forms no longer accommodates the scope of work that is being done for Mycotic disease with the expanded testing capacity and the new scope of work that is being implemented in the next 5-year cycle of the ELC cooperative agreement. . With the expanded increase in the burden of disease, and the use of Attachments 3d and 3e, for Mycotic diseases, the total burden hours for these two forms are estimated at 31,920 burden hours.

Summary of changes and justification for *N.gonorrhoeae* data collection that will be provided to the Program Office of CDC – DSTDP (Attachments 3f – 3g): For the next 5-year ELC cycle, DSTDP will be changing the way surveillance is conducted for *N. gonorrhoeae*. The programs of GISP and SURRG will be recreated into the program of CARGOS. Attachments 3f and 3g are replacing the prior data collection for *N. gonorrhoea*e labeled *AR Lab Network Alert and Monthly Data Report Form for Neisseria gonorrhoeae,* as a result of the creation of the CARGOS program, and this programs need for a different data collection. Additionally, as a result of SHARP funding, additional laboratories have been able to support testing for *N. gonorrhoeae*, increasing the number of reporting labs. The total burden hours for these two forms are estimated at 191 burden hours.

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 in accordance with the Program Offices requirements.

For the Division of Healthcare Quality Promotion data will be shared in the following way, in addition to through annual reports and peer-reviewed manuscripts:

- Data about the CPOs is routinely share on DHQP Patient Safety Portal (arpsp.cdc.gov) for easy public access, download, and visualization.

For the Division of STD Prevention data will be shared in the following way, in addition to through annual reports and peer-reviewed manuscripts:

- Data is shared on the Altus Plus visualization platform (AtlasPlus - Overview (cdc.gov)).
- Data sets are available through data.cdc.gov

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 in the case of descriptions of traditionally healthcare-associated infections. 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.

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 (October 2020)
    d. Public Health Service Act (42 USC 241) Section 301
2. Performance Measures
    a. I.1 – ROUTINE TESTING BY GENERA IN JURISDICTION- Annual Evaluation and Performance Measurement Report
    b. I.2- EXPANDED DRUG SUSCEPTIBILITY TESTING (ExAST) IN JURISDICTION- Annual Evaluation and Performance Measurement Report
    c. I.3- CANDIDA SPECIES IDENTIFICATION IN JURISDICTION- Annual Evaluation and Performance Measurement Report
    d. I.4- HAIAR WHOLE GENOME SEQUENCING (WGS) OF GRAM-NEGATIVE AR THREATS IN JURISDICTION- Annual Evaluation and Performance Measurement Report
    e. I.5- C. AURIS COLONIZATION SCREENING IN JURISDICTION-Annual Evaluation and Performance Measurement Report
    f. I.6- CARBAPENEMASE-PRODUCING ORGANISM (CPO) SCREENING IN JURISDICTION- Annual Evaluation and Performance Measurement Report
    g. I.7- AZOLE RESISTANCE IN CLINICAL ASPERGILLUS FUMIGATUS ISOLATES- Annual Evaluation and Performance Measurement Report

h. I.8- N. GONORRHOEAE WHOLE GENOME SEQUENCING (WGS)- Annual Evaluation and Performance Measurement Report
i. I.9- GONOCOCCAL (GC) ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) IN JURISDICTION- Annual Evaluation and Performance Measurement Report
j. I.10- WHOLE GENOME SEQUENCING (WGS) OF S. PNEUMONAIE -Annual Evaluation and Performance Measurement Report
k. I.11- CLOSTRIDIOIDES DIFFICILE (C. DIFFICLE) TESTING IN JURISDICTION- Annual Evaluation and Performance Measurement Report
l. I.12- ANTIFUNGAL RESISTANT TINEA DERMATOPHYTES -Annual Evaluation and Performance Measurement Report
m. I.13- ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF INVASIVE HAEMOPHILUS INFLUENZAE (H. INFLUENZAE) IN JURISDICTION- Annual Evaluation and Performance Measurement Report
n. I.14- MYCOPLASMA GENTALIUM (MG)- Annual Evaluation and Performance Measurement Report
o. I.15- MOLECULAR Mtb TESTING- Annual Evaluation and Performance Measurement Report
p. I.16- C. AURIS WHOLE GENOME SEQUENCING (WGS) IN JURISDICTION- Annual Evaluation and Performance Measurement Report
q. I.17- MONITORIING CRE CRPA IN COMPANION ANIMALS TO FROM HUMANS- Annual Evaluation and Performance Measurement Report
r. I.18- HEALTHCARE WASTEWATER-BASED SURVEILLANCE - Annual Evaluation and Performance Measurement Report
s. I.19- COMMUNICATION AND COORDINATION OFACTIONABLE EPI LAB DATA IN JURISDICTION- Annual Evaluation and Performance Measurement Report
t. I.20- CHARACTERIZATION OF THE CLINICAL LABORATORY NETWORK IN JURISDICTION-Annual Evaluation and Performance Measurement Report
u. I.21 NEISSERIA GONORRHOEAE ETEST FOR SHARP

3. Data Collection Forms
   a. AR Lab Network Annual Report of Testing Methods for Carbapenemase-producing Organisms
   b. AR Lab Network Monthly Data Report Form for Carbapenemase-producing Organisms
   c. AR Laboratory Network Alert Report Form for Carbapenemase-producing Organisms
   d. AR Lab Network Alert and Monthly Data Report Form for *Candida*
   e. AR Lab Network Form for Phylogenetic Tree-level Mycotics Reporting
   f. AR Lab Network Alert and Monthly Data Report Form for *Neisseria gonorrhoeae*
   g. AR Lab Network DAART data elements for *Neisseria gonorrhoeae*
4. 60 Day Federal Register Notice
5. Summary of CRE/CRPA/CRAB reporting by states
6. ELC AR Lab Network State Testing Activities
7. Summary of *Candida* reporting by states
8. AR Lab Network non-research determination
9. Privacy Impact Assessments
10. GC SHARP Project Non-Research Determination

11. SURRG Project Non-research Determination