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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-23-1310]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the
Centers for Disease Control and Prevention (CDC) has submitted
the information collection request titled "Public Health
Laboratory Testing for Emerging Antibiotic Resistance and Fungal
Threats" to the Office of Management and Budget (OMB) for review
and approval. CDC previously published a "Proposed Data
Collection Submitted for Public Comment and Recommendations"
notice on October 11, 2022 to obtain comments from the public
and affected agencies. CDC received one comment related to the
previous notice. This notice serves to allow an additional 30
days for public and affected agency comments.

CDC will accept all comments for this proposed information
collection project. The Office of Management and Budget is
particularly interested in comments that:

(a) Evaluate whether the proposed collection of information
is necessary for the proper performance of the functions of
the agency, including whether the information will have
practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats (OMB Control No. 0920-1310, Exp. 12/31/2023) – Revision – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).


Background and Brief Description

This collection related to state and local 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, the National Strategy of September 2014 and to implement sub-objective 2.1.1 of the National Action Plan of March 2015 for Combating Antibiotic Resistant Bacteria. Data collected throughout this network is also authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

The Antibiotic Resistance Laboratory Network (AR Lab Network) is made up of jurisdictional public health laboratories in all 50 states, five large cities, and Puerto Rico. These public health laboratories will be equipped to detect and characterize isolates of carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB), as well as carbapenemase-positive organisms (CPOs) from colonization

screening swabs. These resistant bacteria are becoming more and more prevalent, particularly in healthcare settings, and are typically identified in clinical laboratories, but characterization is often limited. The 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 whether carbapenemase-producing organisms are 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, some 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.

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 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 and the community, mount a comprehensive local response, and better understand these deadly threats to quickly contain them. Additionally, a subset of jurisdictions will participate in detection and characterization of AR *Neisseria gonorrhoeae*, including antimicrobial susceptibility testing of *Neisseria gonorrhoeae.*

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 summary report describing testing methods and volume. 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 Evaluation and Performance Measurement Report 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, at least monthly, by CSV or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to: (a) provide data for state and local infection prevention programs; (b) identify new types of antibiotic resistant organisms; (c) identify new resistance mechanisms in targeted organisms; (d) describe the spread of targeted resistance mechanisms; and (e) identify geographical distribution of antibiotic resistance or other epidemiological trends.

4. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC and submitting facilities and clinical laboratories. For messaging to CDC, these 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 or results while simultaneously lessening burden on public health laboratories.

5. Detection of targeted resistant organisms and resistance 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 its testing results to date.

Sites participating in *Candida* identification testing and C. auris whole genome sequencing (WGS) 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 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 candida identification testing results to CDC, 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. Participating laboratories will report all *C. auris* WGS testing results to CDC by REDCap or Health Level 7 (HL7) using online web-portal transmission. This information

will be used to (1) support outbreak investigations (i.e., helping to identify new introductions and ongoing or undetected transmission), (2) monitor circulating clades and strains, and (3) learn more about mechanisms of antifungal resistance. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC and coordinating epidemiologists. For messaging to CDC, these messaging protocols will be based in REDCap or the AIMS platform.

4. 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.

Sites participating in detection and characterization of AR
Neisseria gonorrhoeae, including antimicrobial susceptibility
testing of *Neisseria gonorrhoeae* will provide the following to
the STD Laboratory Reference and Research Branch (SLRRB) at CDC
- Division of STD Prevention (DSTDP):

1. Annually, participating laboratories will provide an
   Evaluation and Performance Measure Report. Data will be
   used to indicate progress made toward program objectives
   and challenges encountered.

2. Participating laboratories will notify CDC DTSDP of any
   isolate(s) identified to demonstrate an "alert" MIC as
   defined by SLRRB within one working day. 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.

3. Participating laboratories will report all testing results
   to CDC, requested at least monthly, by email, REDCap, or
   Health Level 7 (HL7) using an online web-portal
   transmission. This information will be used to (1) identify
   and track antibiotic resistant pathogens and emerging
   patterns of resistance, and (2) aid public health
   departments and healthcare facilities in timely responding
   to antibiotic resistant 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.

CDC requests OMB approval for an estimated 4,950 annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

| Type of Respondents | Form name | Number of Respondents | Average Number of Responses per Respondent | Average Burden per Response (in hours) |
|---|---|---|---|---|
| Public Health Laboratories | 3a. Annual Report of Bacterial Specimen Testing Methods | 56 | 1 | 6/60 |
| Public Health Laboratories | 3b. Annual Evaluation and Performance Measurement Report for Bacterial Specimen Testing | 56 | 1 | 4 |

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| Public Health Laboratories | 3c. Monthly Data Report Form for Bacterial Specimen Testing | 56 | 12 | 4 |
| Public Health Laboratories | 3d. AR Lab Network Alerts—Bacterial Specimen Testing | 56 | 34 | 6/60 |
| Public Health Laboratories | 3e. Annual Evaluation and Performance Measurement Report (*Candida* identification) | 56 | 1 | 2 |
| Public Health Laboratories | 3f. Monthly Data Report Form for *Candida* identification | 56 | 12 | 2 |
| Public Health Laboratories | 3g. AR Lab Network Alerts Report Form for *Candida auris* | 56 | 13 | 6/60 |
| Public Health Laboratories | 3h. Annual Evaluation and Performance Measurement Report (*Neisseria gonorrhoeae*) | 56 | 1 | 1 |
| Public Health Laboratories | 3i. AR Lab Network Alert and Monthly Data Report Form for *Neisseria gonorrhoeae* | 56 | 12 | 6/60 |

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|---|---|---|---|---|
| Public Health Laboratories | 3j. Annual Evaluation and Performance Measurement Report (*C. auris* Whole Genome Sequencing) | 56 | 1 | 1 |
| Public Health Laboratories | 3k. AR Lab Network Form for Isolate/Specimen-level Mycotics Testing (C. auris Whole Genome Sequencing) | 56 | 12 | 6/60 |
| Public Health Laboratories | 3l. AR Lab Network Form for Phylogenetic Tree-level Mycotics Reporting (C. auris Whole Genome Sequencing) | 56 | 12 | 6/60 |

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