# Project Determination

## GC SHARP Expansion of rapid gradient strip antibiotic sensitivity testing, whole genome sequencing, and molecular detection assays for clinical management and local strain surveillance of gonorrhea

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| **Project ID:** | 0900f3eb81ff52e2 |
| **Accession #:** | NCHHSTP-STDLRRB-10/4/22-f52e2 |
| **Project Contact:** | Jennifer Reimche |
| **Organization:** | NCHHSTP/DSTDP/STDLRRB |
| **Status:** | Project In Progress |
| **Intended Use:** | Project Determination |
| **Estimated Start Date:** | 10/31/22 |
| **Estimated Completion Date:** | 07/31/29 |
| **CDC/ATSDR HRPO/IRB Protocol#:** | |
| **OMB Control#:** | |

## Description

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|---|
| **Priority** |
| Standard |
| **Date Needed** |
| 10/31/22 |
| **Determination Start Date** |
| 10/05/22 |
| **Description** |
| The Division of STD Prevention in collaboration with the Antibiotic Resistance Coordination Strategy Unit (ARx) is supporting state and local public health laboratories, as a part of the Antimicrobial Resistance Laboratory Network (ARLN), to build capacity for rapid gradient strip antibiotic susceptibility testing (AST), |

with the option to perform whole genome sequencing (WGS) and/or molecular detection of antimicrobial resistance (AR) markers. Funding for expansion of these activities comes from the American Rescue Plan under the Strengthening HAI/AR Program Capacity supplement (SHARP) Project II. To enhance clinical management of gonorrhea, clinicians or laboratories will be able to submit gonorrhea specimens or isolates for CLIA-compliant testing for azithromycin, cefixime, ceftriaxone, and ciprofloxacin susceptibility to their state, county, or other public health laboratory. Specimens will be accepted from cases such as routine AST, potential treatment failure (e.g. where a patient persistently tests positive and has continued symptoms after therapy and reinfection has been ruled out by clinical assessment), test of cure, suspected exposure, or disseminated gonococcal infection. Depending on specimen volume and operational considerations, some of the isolates or specimens will be routed to regional AR laboratories, i.e., ELC-funded public health laboratories that perform gonorrhea AR laboratory testing in other DSTDP projects such as GISP, eGISP, and SURRG, as described and approved in other project determinations for these projects. CDC will collect delinked data associated with submissions made to either SHARP-funded sites or the regional laboratories in order to monitor occurrences of cephalosporin non-susceptible isolates and for program evaluation of the lab's capacity to implement testing in their jurisdiction, monitor their progress, and determine where they face challenges. Isolates at CDC will be used for confirmatory antibiotic sensitivity testing (using the gold standard agar dilution method) and, where appropriate, whole genome sequencing and AR marker molecular assays. Data generated at the public health laboratories may be used locally for surveillance and public health response. Collection of data by CDC will enhance surveillance and understanding of gonorrhea cases of concern.

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission**

No

**IMS Activation Name**

Not selected

**Select the primary priority of the project**

Not selected

**Select the secondary priority(s) of the project**

Not selected

**Select the task force associated with the response**

Not selected

**CIO Emergency Response Name**

Not selected

**Epi-Aid Name**

Not selected

**Lab-Aid Name**

Not selected

**Assessment of Chemical Exposure Name**

Not selected

**Goals/Purpose**

The purpose of this project is to support and expand access to rapid antimicrobial susceptibility testing for clinical management of gonorrhea to the state and local public health laboratory level, especially in cases where test of cure (e.g. in pharyngeal infections) reveals persistent infection despite recommended treatment and when reinfection has been ruled out. Increased testing will enhance surveillance of gonorrhea cases with reduced susceptibility to antibiotics at CDC and the state or local public health lab level. Rapid antimicrobial susceptibility testing under CLIA at the public health labs will enable results to be reported to submitters to improve patient care and public health practice. Supporting the development of whole genome sequencing workflows at state public health labs will empower more jurisdictions to perform their own genomic analyses to augment local response. The use of molecular AR marker assays in the STD Laboratory Reference and Research Branch (SLRRB) at CDC, and eventually at AR Laboratory Network regional labs, will enable more rapid detection of AR markers for use when culture is not possible, or an outbreak of non-susceptible N. gonorrhoeae may be suspected. This program will help expand access to these tests to more jurisdictions throughout the country and enhance experience in gonorrhea testing at the state and local public health laboratory level.

**Objective**

1) To evaluate the implementation of testing at state and local public health labs DSTDP will collect data associated with testing submissions (eg. How many submitters and testing turn-around-time); this may inform testing program planning and expansion in the future. 2) To augment surveillance of antimicrobial resistance gonorrhea and support state and local public health practice CDC will be notified of isolates of concern (those with cephalosporin minimum inhibitory concentrations above a define threshold) within 24 hours, and CDC may request the isolates be shared for confirmatory testing and additional molecular characterization at SLRRB. 3) Sequencing IDs and NCBI SRA BioSample IDs will be shared with SLRRB for isolates of concern that are analyzed by whole genome sequencing at participating public health laboratories. 4) SLRRB will support state and local public health labs with the expansion of GC testing and investigation of isolates of concern to facilitate local surveillance and enhance public health practice.

**Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities?**

Yes

**Project does not incorporate elements of health equity science**

Yes

**Measuring Disparities**

Not selected

**Studying Social Determinants of Health (SDOH)**

Not selected

**Assessing Impact**

Not selected

**Methods to Improve Health Equity Research and Practice**

Not selected

**Other**

Not selected

**Activities or Tasks**

Secondary Data or Specimen Analysis; Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials

**Target Population to be Included/Represented**

General US Population; Other-Disadvantaged persons and populations who are disproportionally affected by STIs

**Tags/Keywords**

Gonorrhea; Treatment Failure; Sexually Transmitted Diseases, Bacterial

**CDC's Role**

CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens; CDC is providing funding

**Method Categories**

Secondary Data Analysis; Secondary Specimen Analysis

**Methods**

Submitting providers and laboratories will request testing of isolates/specimens collected during a clinical encounter (no additional specimens will be collected). AST will be conducted under CLIA compliance by the participating AR Laboratory Network labs using gradient strip antimicrobial susceptibility testing. Specimen data will be entered into a web-portal (REDCap) and only deidentified data will be shared with CDC. Copies of frozen isolate stocks will be stored at SLRRB or archived at the CDC Biorepository; copies of isolates of concern may also be submitted to the AR Isolate Bank. SLRRB may confirm isolate identification and perform confirmatory AST (gold-standard agar dilution, as well as Etest), whole genome sequencing, and molecular assays for AR markers on the isolates of concern.

**Collection of Info, Data, or Bio specimens**

Specimen data will be entered into a web-portal and only delinked data will be shared with CDC. Specific data fields include patient age, gender, travel history, state of submitting facility, collection date, specimen source, date specimen received for testing, reason for testing, treatment administered to patient (if suspected treatment failure), minimum inhibitory concentrations, and sequencing ID (if applicable). Isolates with concerning reduced antibiotic susceptibility will be shared with CDC by the labs as frozen stocks. Jurisdictions that perform whole genome sequencing will upload raw, quality-controlled sequencing data to NCBI Sequence Read Archive (SRA) where it will be publicly available; sequencing IDs for isolates will be assigned by SLRRB or the jurisdiction will share the IDs with SLRRB (via emailed form or REDCap). Any confirmatory data generated by SLRRB and shared with the state/local public health labs will not be incorporated into patient records. WGS data generated at SLRRB will be uploaded to NCBI within 120 days of generating the data. Frozen stocks of isolates of concern will be stored at CDC.

**Expected Use of Findings/Results and their impact**

Specimen data will be used to determine the utility of offering rapid AST services. Information such as reasons for testing request, specimen sources, etc. may provide important insight on improved ways to direct public health resources for antibiotic resistant gonorrhea control and prevention. Genetic characterization of isolates with reduced antibiotic susceptibility associated with treatment failure cases could help identify circulating strain types or resistance markers which in turn could inform surveillance strategies.

**Could Individuals potentially be identified based on Information Collected?**

Yes

**Will PII be captured (including coded data)?**

Yes

| Does CDC have access to the Identifiers (including coded data)? |
|---|
| No |
| **Is this project covered by an Assurance of Confidentiality?** |
| No |
| **Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** |
| No |
| **Is there a formal written agreement prohibiting the release of identifiers?** |
| Yes |

## Funding

| Funding Type | Funding Title | Funding # | Original Fiscal Year | # of Years of Award | Budget Amount |
|---|---|---|---|---|---|
| CDC Cooperative Agreement | Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases | CK19-1904 | 2019 | 5 | |

## HSC Review

| HSC Attributes |
|---|
| **Other - This project activity involves secondary data analysis to support and expand access to rapid antimicrobial susceptibility testing for clinical management of gonorrhea to the state and local public health laboratory.** |
| Yes |

## Regulation and Policy

| Do you anticipate this project will be submitted to the IRB office |
|---|
| No |

## Institutions

| Institution | FWA # | FWA Exp. Date | IRB Title | IRB Exp. Date | Funding # |
|---|---|---|---|---|---|

## Staff

| Staff Member | SIQT Exp. Date | Citi Biomedical Exp. Date | Citi Social and Behavioral Exp. Date | Citi Good Clinical Exp. Date | Staff Role | Email | Phone # | Organization/ Institution |
|---|---|---|---|---|---|---|---|---|
| Cau Pham | 09/23/2025 | 01/07/2022 | | 04/22/2022 | Technical Monitor | whi4@cdc.gov | 404-718-5642 | STD LABORATORY REFERENCE & RESEARCH BRANCH |
| Ellen Kersh | 10/22/2024 | 02/01/2025 | | | Program Lead | egk6@cdc.gov | 404-639-2728 | STD LABORATORY REFERENCE & RESEARCH BRANCH |
| Jennifer Reimche | 09/14/2025 | 10/21/2025 | | | Principal Investigator | nkv3@cdc.gov | 404-718-7985 | STD LABORATORY REFERENCE & RESEARCH BRANCH |
| John Cartee | 10/04/2025 | 01/07/2022 | | | Co-Investigator | yil5@cdc.gov | 404-639-3826 | GENETIC PHYLOGENY |

## DMP

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| **Proposed Data Collection Start Date** | 10/31/22 |
| **Proposed Data Collection End Date** | 07/31/29 |
| **Proposed Public Access Level** | Public |
| **Public Access justification** | Aggregated summaries of data collected may be made public through publications and presentations to help expand capacity for rapid AST for clinical management of gonorrhea. Genetic/genomic data associated with any isolates sequenced will be released consistent with agency policies. |

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| **How Access Will Be Provided for Data** | CDC will not receive any personal identifiers for specimens tested. All line-listed data (which does not contain PII) is housed on CDC servers with restricted access that is limited to project staff. |
| **Plans for archival and long-term preservation of the data** | Specimen data will be stored electronically in restricted access storage locations. Isolates shared with CDC will be archived at CDC. |

## Spatiality (Geographic Location)

| Country | State/Province | County/Region |
|---|---|---|
| United States | | |

## Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|---|---|
| HSC:<br>**Does NOT Require HRPO Review** | Not Research - Public Health Surveillance<br><br>*45 CFR 46.102(l)(2)*<br><br>Research Not Involving Human Subjects<br><br>*45 CFR 46.102(e)* | 10/11/22 | Dodson_Janella R. (jhd7) CIO HSC |
| PRA:<br>**PRA does not apply** | **Qualifies for a regulatory exclusion:** No Information being collected<br>*Justification:* OMB PRA is not applicable to this secondary de-linked data / specimen analysis. No new data are being collected. | 10/12/22 | Bonds_Constance (akj8) CTR OMB/PRA Coordinator |
| ICRO:<br>**Concur** | | 10/12/22 | Zirger_Jeffrey (wtj5) ICRO Reviewer |