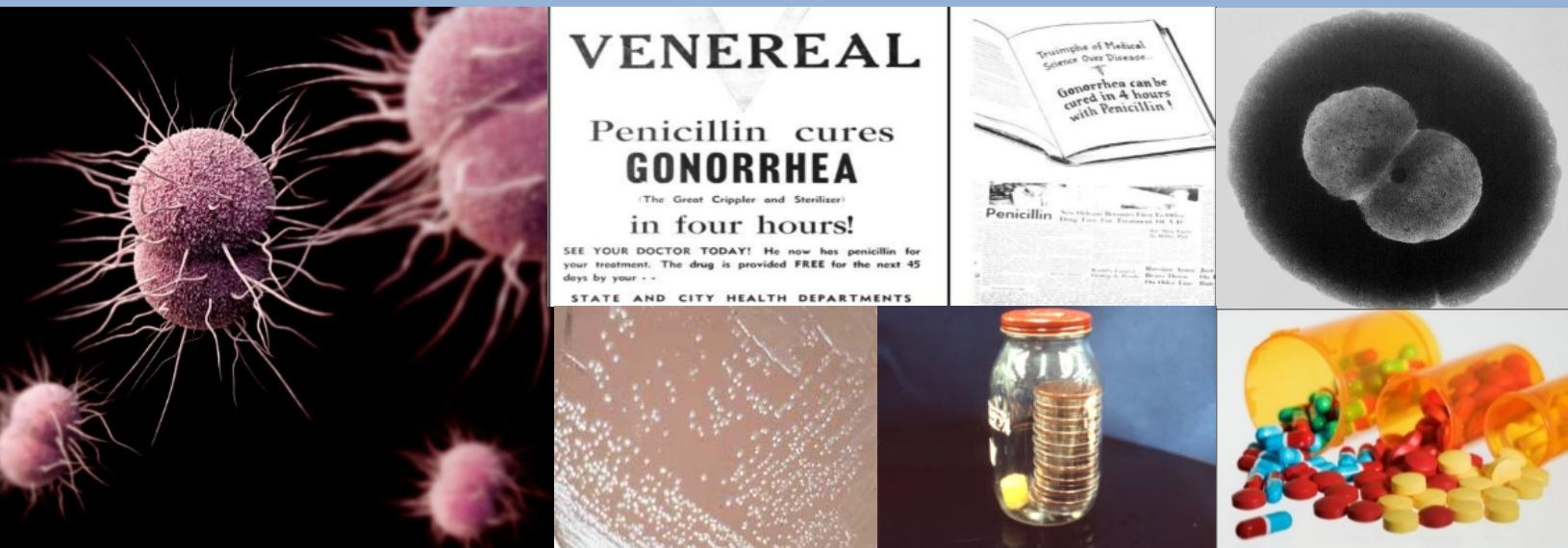


# Gonococcal Isolate Surveillance Project (GISP) and Enhanced GISP (eGISP)



## Protocol

# Table of Contents

CDC Principal Investigators	3
1. Introduction	4
1.1. Background	4
1.2 GISP and eGISP Funded Jurisdictions	5
1.3. Objectives	6
2. Methods	6
3. Activities and Responsibilities	7
3.1. Sentinel Sites	8
3.2. ARLN Laboratories	23
3.3. Centers for Disease Control and Prevention	26
4. General Project Issues	28
4.1. Quality Assurance	28
4.2. Human Subjects	28
4.3. Office of Management & Budget	28
4.4. Publication of GISP/eGISP Data	28
4.5. Use of GISP/eGISP Isolates and Data	29
5. Clinical/Demographic Data Elements	30
5.1 Core GISP Data Elements	30
5.2 Enhanced GISP (Part A) Data Elements	37
6. Contact Information and Mailing Addresses	39
6.1. CDC Project Personnel	39
6.2 ARLN Project Laboratory Personnel	42
Appendix A: Naming Conventions	45
Appendix B: Instructions for Use of CDC Private File Transfer Portal (FTP)	46

## Tables and Figures:

Table 1. GISP and eGISP jurisdictions and sites	6
Table 2. Summary of Responsibilities and Timelines for Project Participants	8
Table 3. Manifest Data Elements	15
Table 4. Facility Location Codes	16
Figure 1. GISP/eGISP Manifest for <i>N. gonorrhoeae</i>	17
Figure 2. eGISP Manifest for <i>N. meningitidis</i>	17
Table 5. Sentinel Site Codes	19
Table 6. ARLN Assignments for GISP and eGISP	24

# **CDC Principal Investigators**

**Sancta St. Cyr, MD MPH**

GISP Project Officer

Surveillance & Data Science Branch

Division of STD Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention

Atlanta, Georgia

**Kristen Kreisel, PhD**

Surveillance & Data Science Branch

Division of STD Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention

Atlanta, Georgia

**Cau Pham, PhD**

STD Laboratory Reference & Research Branch

Division of STD Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention

Atlanta, Georgia

**Brian Raphael, PhD**

STD Laboratory Reference & Research Branch

Division of STD Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Centers for Disease Control and Prevention

Atlanta, Georgia

# 1. Introduction

## 1.1. Background

In 2019, Gonorrhea was the second most commonly reported notifiable disease in the United States (US) with over 616,392 cases reported to the Centers for Disease Control and Prevention (CDC). The treatment and control of infections due to *Neisseria gonorrhoeae* have been complicated by the organism's ability to acquire antimicrobial resistance. The Gonococcal Isolate Surveillance Project (GISP), established in 1986, has functioned as the national surveillance system of antibiotic resistant gonorrhea in the US. It was established not only to monitor susceptibility trends in *N. gonorrhoeae* strains, but also to function as a rational basis for the selection of gonococcal therapies. GISP data of susceptibility trends from male gonococcal urethral isolates have provided critical data for the CDC's STD Treatment Guidelines, directly informing gonorrhea treatment recommendations in 1989, 1993, 1998, 2002, 2006, 2007, 2010, 2012, 2015, 2020, and 2021.

In 2013, CDC released *Antibiotic Resistance Threats in the United States*, the first report to look at the burden and threats posed by antibiotic resistance on human health, which named antibiotic-resistant gonorrhea among the three most urgent threats of its kind in the country. This report was later updated in 2019 and maintained gonorrhea as one of its urgent threats in the US. In 2014, the White House developed the *National Strategy to Combat Antibiotic-Resistant Bacteria* (CARB), calling for the prevention, detection, and control of antibiotic resistance. Using CARB funds, the Antimicrobial Regional Laboratory Network (ARLN), a network of seven regional public health laboratories that provides cutting-edge antimicrobial resistance laboratory support, was established in 2016.

The CDC Division of STD Prevention (DSTD) supports activities that aim to slow the development of antimicrobial-resistant (AMR) gonorrhea and prevent its spread. To build robust capacity for culture-based antimicrobial susceptibility testing (AST) and genomic sequencing of *N. gonorrhoeae* isolates, four laboratories in the ARLN were funded for *N. gonorrhoeae* activities. Starting in 2017, these four laboratories began functioning as the regional laboratories for GISP.

In 2017, GISP was also expanded in a subset of clinical sites to conduct *N. gonorrhoeae* surveillance in non-urethral isolates (i.e., pharyngeal, rectal, and endocervical isolates) and to evaluate the burden of urethritis/cervicitis associated with *N. meningitidis* through surveillance of urethral and non-urethral isolates. The Enhanced Gonococcal Isolate Surveillance Program (eGISP) was established to help understand if the pharynx and/or rectum may be anatomic niches that select for or foster resistance and to evaluate if gonococcal susceptibility patterns may vary between men and women.

Additionally, *Neisseria* species, including the two pathogens *N. gonorrhoeae* and *N. meningitidis*, have similar morphology on culture and Gram stain, requiring species-specific confirmatory tests to distinguish the *Neisseria* species. Given that *N. meningitidis* urethritis/cervicitis is not a reportable disease in the US, and that labs do not routinely test genitourinary specimens for *N. meningitidis*, additional data on the epidemiology and biology of *N. meningitidis* urethritis/cervicitis are needed.

In 2021, a new surveillance component was added to eGISP to include the evaluation of known resistance-associated genetic markers from remnant nucleic acid amplification tests (NAAT). This molecular surveillance project was added to improve the identification of resistant gonorrhea in a culture-independent manner. Culture remains the best way to detect novel AMR mutations in gonorrhea, but molecular surveillance has the potential to increase the availability of resistant gonorrhea detection in the US, especially in locations without culture capacity.

GISP continues to be the core surveillance system in the US for resistant gonorrhea. Expanding GISP may improve the ability to detect changes in susceptibility patterns, detect resistant infections sooner and inform efforts to maximize surveillance specificity. This updated protocol supersedes all previous project protocols.

## 1.2 GISP and eGISP Funded Jurisdictions

The following state, territory, and city health departments successfully competed for funding under Epidemiology and Laboratory Capacity (ELC) Program CDC-RFA-CK19-1904 and were subsequently awarded funding in 2021 under the ELC Notice of Funding Opportunity announcement for GISP and eGISP (Part A and Part B) activities.

GISP jurisdictions are funded to monitor antimicrobial susceptibility of *Neisseria gonorrhoeae* by collecting at least 25 urethral specimens each month from men with symptomatic gonococcal urethritis. While all participating jurisdictions are considered GISP sites, a subset of GISP sites (See Table 1. *GISP and eGISP Jurisdictions and sites*) have been additionally funded to participate in one or both eGISP activities, which include 1) the collection of extragenital specimens from men and women and endocervical specimens from women; and 2) the collection of remnant NAAT samples associated with submitted GISP and/or eGISP gonococcal cultures. Additionally, funded eGISP (Part A) sites may choose to also participate in the optional activities involving the collection of culture specimens presumed to be *Neisseria meningitidis*.

State, territory, and city health departments that were awarded funding for Strengthening U.S. Response to Resistant Gonorrhea (SURRG) through the ELC Program CDC-RFA-CK19-1904 announcement follow similar protocols for the collection of urethral specimens from men with symptomatic gonococcal urethritis seeking care in STD clinics. The first 25 male urethral isolates from these sites are also included in GISP analyses.

Table 1. GISP and eGISP Jurisdictions and Sites

ELC Jurisdiction	Sentinel Site	GISP	eGISP (Part A)	eGISP (Part B)
		<i>culture-based surveillance</i>	<i>culture-based surveillance</i>	<i>molecular surveillance</i>
Alabama	Birmingham	✓		
Alaska	Anchorage	✓		
Arizona	Phoenix	✓	✓	
California	Orange County	✓	✓	
	San Diego	✓	✓	✓
	San Francisco	✓		
Chicago, IL	Chicago	✓		✓
Colorado	Denver	✓		
District of Columbia	Washington, D.C.	✓		
Hawaii	Honolulu	✓		✓
	Tripler Army Medical Center	✓		
Indiana	Indianapolis	✓		
Los Angeles, CA	Los Angeles	✓		
Louisiana	New Orleans	✓	✓	✓
Maryland	Baltimore	✓		
Michigan	Pontiac	✓		✓
Minnesota	Minneapolis	✓		
Missouri	Kansas City	✓		
Nevada	Las Vegas	✓	✓	✓
New Mexico	Albuquerque	✓		
New York	Buffalo	✓		
New York City, NY	New York City	✓		
North Carolina	Greensboro	✓		
Ohio	Cleveland	✓		
	Columbus	✓	✓	

Oregon	Portland	✓		✓
Pennsylvania	Pittsburgh	✓		
Philadelphia, PA	Philadelphia	✓	✓	
Texas	Dallas	✓		
Washington	Seattle	✓		
Wisconsin	Milwaukee	✓		

\*All eGISP (Part A and Part B) sentinel sites are expected to participate in core GISP activities as described in the protocol.

## 1.3. Objectives

### GISP (culture-based surveillance)

1. To monitor *N. gonorrhoeae* antimicrobial susceptibilities trends
2. To characterize male patients with urethral gonorrhea attending STD clinics, particularly those infected with *N. gonorrhoeae* that are not susceptible to recommended antimicrobials
3. To phenotypically characterize isolates to describe the diversity of *N. gonorrhoeae* antimicrobial resistance

### eGISP (Part A: culture-based surveillance)

1. To monitor *N. gonorrhoeae* antimicrobial susceptibilities trends in male and female patients with extra-genital gonorrhea, and female patients with endocervical gonorrhea attending STD clinics
2. To characterize male patients with urethral gonorrhea, male and female patients with extra-genital gonorrhea, and female patients with endocervical gonorrhea attending STD clinics, particularly those infected with *N. gonorrhoeae* that are not susceptible to recommended antimicrobials
3. To phenotypically characterize isolates to describe the diversity of *N. gonorrhoeae* antimicrobial resistance in male and female patients with extra-genital gonorrhea, and female patients with endocervical gonorrhea attending STD clinics

### eGISP (Part B: molecular surveillance)

1. To identify and monitor genetic markers associated with antimicrobial resistance in *N. gonorrhoeae* using remnant NAATs from males with urethral gonorrhea, females with endocervical gonorrhea, and males and females with extragenital gonorrhea.
2. To characterize male and female patients with genital and extragenital gonorrhea, particularly those infected with *N. gonorrhoeae* that demonstrate genetic mutations associated with antimicrobial resistance to recommended therapies

### eGISP (optional activity)

1. To evaluate the burden of urethritis and cervicitis associated with *N. meningitidis*
2. To characterize male patients with urethral and/or extra-genital *N. meningitidis*, and female patients with endocervical and/or extra-genital *N. meningitidis*
3. To characterize isolates from different anatomic sites, to describe the strain diversity and antimicrobial susceptibility patterns of selected *N. meningitidis* isolates among this population

## 2. Methods

GISP and eGISP are collaborations between the CDC Division of STD Prevention (DSTDP): Surveillance & Data Science Branch (SDSB) and the STD Laboratory Reference & Research Branch (STDLRRB); Antibiotic Resistance Laboratory Network (ALRN) regional laboratories; and selected U.S. public health STD programs and associated STD specialty care clinics and local public health laboratories (“sentinel sites”). The responsibilities of each group of participants are detailed in this protocol.

GISP analyses are based on clinical, demographic, and isolate antimicrobial susceptibility data from the first 25 symptomatic male patients attending participating sentinel sites each month who have been identified to have a positive urethral culture for *N. gonorrhoeae*.

eGISP (Part A) analyses are based on clinical, demographic, and isolate antimicrobial susceptibility data from the following:

- Isolates from the first 25 symptomatic male patients attending participating sentinel sites each month who have been identified to have a positive urethral gonococcal culture and a positive urethral/urine gonorrhea nucleic acid amplification test (NAAT) specimen
- Isolates from the first 25 male and female patients attending participating sentinel sites each month who have been identified as having a positive pharyngeal and /or rectal gonococcal culture and a corresponding positive pharyngeal and/or rectal gonorrhea NAAT
- Isolates from the first 25 female patients attending participating sentinel sites each month who have been identified as having positive endocervical gonococcal culture and NAAT. A urine specimen or vaginal specimen for NAAT is acceptable.
- All urethral and rectal isolates from male patients and all endocervical and rectal isolates from female patients that demonstrate bacterial growth by culture consistent with *Neisseria* species, but with negative gonorrhea NAAT results, and are suspected to be *N. meningitidis* (**optional eGISP activity**)

eGISP (Part B) analyses are based on antimicrobial resistance-associated mutations data from molecular testing of remnant NAAT samples corresponding to submitted gonorrhea-positive cultures from GISP or eGISP (Part A: culture-based surveillance).

See section 3.1.2.1 on Target populations for isolate collection

### 3. Activities and Responsibilities

Table 2. Summary of Responsibilities and Timelines for Project Participants

Project Participant	Activity	Timeline
Sentinel Sites	Clinical and Demographic Data: Collect clinical and demographic data and submit to CDC (via SAMS)	<b>Monthly</b> - No more than 4 weeks after the end of the month of collection
	Manifest: Complete and submit shipping manifest to assigned ARLN (Include hardcopy of manifest in box with the isolates; transmit electronic copy via FTP)	<b>Monthly</b> - no later than the <b>first Monday</b> of the month following the month of collection
	Isolates: Collect and submit <i>N. gonorrhoeae</i> isolates to assigned ARLN laboratory (Include hardcopy of manifest in box)	<b>Monthly</b> - no later than the <b>first Monday</b> of the month following the month of collection
	Isolates (Optional eGISP activity): Collect and submit <i>N. meningitidis</i> isolates to CDC STD	Monthly

	Laboratory Reference & Research Branch (STDLRRB)	
	Remnant NAATs: Collect and submit remnant NAAT samples corresponding to GISP or eGISP gonorrhea-positive isolates directly to CDC STDLRRB (include hardcopy of manifest in box)	Monthly
	Annual Progress Report: Complete and submit annual progress report to ELC Program CDC-RFA-CK19-1904	Annually
<hr/>		
ARLN Laboratory	Testing of Isolates: Perform antimicrobial susceptibility testing on all submitted isolates	Within <b>3 weeks</b> of receipt of isolates
	Susceptibility Test Data: Alert results and batched results should be reported to CDC and sentinel sites	Alert results: within <b>24 hours</b> of confirmation Batched results: <b>monthly</b>
	Shipping of Batched Alert Isolates: Ship batched alert isolates to CDC	Quarterly
	Shipping of Selected Quick-Send Isolates: Ship quick-send isolates to CDC	Ad Hoc
	Shipping of Archive Isolates: Ship all isolates for archive to CDC	Bi-annually
	Shipping of Possible Nm Isolates: Ship all <i>N. meningitidis</i> identified at the ARLN lab to CDC	Monthly
<hr/>		
CDC	Testing of Remnant NAATs: Perform testing of select known resistance- associated molecular markers on all submitted remnant NAAT samples	<b>Quarterly</b>
	Data Files for Sentinel Sites: Provide sentinel sites with electronic GISP and eGISP data file	<b>Upon request</b> for prior year data after August
	Annual Sentinel Site Reports: Publish annual GISP Profiles and eGISP Sentinel Site Reports and make them available to all sites	<b>Fall/Winter</b> following the year of isolate collection

## 3.1. Sentinel Sites

### 3.1.1. Overview

#### GISP (culture-based surveillance)

A GISP sentinel site is responsible for the monthly collection and submission of the first 25 urethral gonococcal isolates from symptomatic men to its assigned Antimicrobial Resistance Laboratory Network (ARLN) regional laboratory. Clinical/demographic data on GISP patients are also collected by GISP sentinel sites and submitted to CDC monthly.

To participate in GISP, the sentinel STD specialty care clinics are required to routinely use gonococcal culture in lieu of or in addition to non-culture testing (i.e., NAAT) on all eligible patients.

At each GISP sentinel site, a primary point of contact (POC) is identified for communication with CDC. The GISP sentinel site POC coordinates with clinical and laboratory staff at the sentinel site responsible for isolate collection and staff responsible for clinical/demographic data collection. The sentinel site GISP POC should ensure that GISP timelines are followed and that isolates are sent to the assigned ARLN laboratory and the clinical/demographic data are sent to CDC.

#### eGISP (Part A: culture-based surveillance)

In addition to GISP activities, an eGISP (Part A) sentinel site is responsible for the monthly collection and submission of isolates to its assigned ARLN regional laboratory including:

- Isolates from the first 25 male and female patients attending participating sentinel sites each month who have been identified as having a positive pharyngeal and/or rectal gonococcal culture and a corresponding positive pharyngeal and/or rectal gonorrhea NAAT
- Isolates from the first 25 female patients attending participating sentinel sites each month who have been identified as having positive endocervical gonococcal culture and NAAT. A urine specimen or vaginal specimen for NAAT is acceptable.
- All urethral and rectal isolates from male patients and all endocervical and rectal isolates from female patients that demonstrate bacterial growth by culture consistent with *Neisseria* species, but with negative gonorrhea NAAT results, and are suspected to be *N. meningitidis* (**optional eGISP activity**)

To participate in eGISP (Part A), the sentinel STD specialty care clinics are required to routinely use gonococcal culture in addition to non-culture testing (i.e., NAAT) on all eligible patients. Clinical/demographic data on eGISP patients are collected by eGISP sentinel sites and submitted to CDC monthly.

At each eGISP (Part A) sentinel site, a primary point of contact (POC) is identified for communication with CDC; this is generally the same POC for GISP activities at the sentinel site. The sentinel site eGISP POC coordinates with clinical and laboratory staff at the sentinel site responsible for isolate collection and staff responsible for clinical/demographic data collection. The sentinel site POC should ensure that GISP and eGISP timelines are followed and that isolates are sent to the assigned ARLN laboratory or the CDC STDLRRB (for *N. meningitidis optional eGISP activity*) and the clinical/demographic data are sent to CDC.

#### eGISP (Part B: molecular surveillance)

An eGISP (Part B) sentinel site is responsible for the monthly collection and submission of remnant NAAT samples corresponding to all submitted GISP or eGISP (Part A) gonococcal isolates directly to CDC. All eGISP (Part B) sites must participate in all GISP activities including the monthly collection and submission of the first 25 urethral gonococcal isolates from symptomatic men and the associated clinical/demographic data on all GISP patients. In addition to GISP activities, eGISP (Part B) sentinel sites must collect a NAAT sample from the same patient at the same clinic visit as the gonococcal culture collection for GISP. Some eGISP (Part B) sentinel sites may also be selected to participate in eGISP (Part A), which includes the collection of gonococcal isolates from the first 25 female patients with genital infections and the first 25 female or male patients with extragenital infections each month. The collection of gonococcal cultures and corresponding NAAT samples are required activities in eGISP (Part A). For eGISP (Part B) sentinel sites, all remnant NAAT samples corresponding to a GISP or an eGISP gonococcal culture, regardless of NAAT result, should be submitted monthly to CDC for molecular testing of known resistance-associated mutations.

To participate in eGISP (Part B), the sentinel STD specialty care clinics are required to routinely conduct gonococcal culture-independent testing (i.e., NAAT) on all eligible patients.

At each eGISP (Part B) sentinel site, a primary point of contact (POC) is identified for communication with CDC; this is generally the same POC for GISP or eGISP (Part A) activities at the sentinel site. The sentinel site POC coordinates with clinical and laboratory staff at the sentinel site responsible for remnant NAAT sample collection. The sentinel site POC should ensure that GISP and eGISP timelines are followed and that remnant NAAT samples are sent to the CDC STDLRRB.

#### **3.1.2. Sentinel Site Specimen Collection, Handling, and Shipping of Isolates and Assignment of Person and Isolate Identifiers**

### **3.1.2.1 Sentinel Site Specimen Collection: Target Populations**

#### GISP

Urethral specimens (based on a presumptive\* or confirmed *N. gonorrhoeae* identification) are collected from the first 25 men with urethral gonococcal infection who present with symptomatic urethritis each month. Because there may be occasional month-to-month variability in the number of isolates submitted, a sentinel site may provide more than 25 isolates in any given month to make up for providing fewer than 25 isolates in other months; the overall goal is for each sentinel site to provide at least 300 isolates per year.

\*A presumptive identification of *N. gonorrhoeae* is based on the following criteria: (i) growth of typical appearing colonies with typical morphologies (e.g., small, transparent) on a selective medium such as Thayer-Martin at 35° C to 36.5° C in 5% CO<sub>2</sub>, (ii) a positive oxidase test, and (iii) the observation of Gram-negative, oxidase-positive diplococci in stained smears.

#### eGISP (Part A: culture-based surveillance)

Urethral specimens (based on a presumptive\* or confirmed *N. gonorrhoeae* identification) are collected from the first 25 men with symptomatic urethral gonococcal infection each month. These are the same men that are included for GISP. Therefore, no additional male urethral isolates are needed from sites participating in eGISP (Part A) activities.

Rectal and pharyngeal isolates are collected from consecutive men and women presenting in the clinic who report rectal and/or pharyngeal exposure who are having a NAAT performed until 25 rectal and/or pharyngeal isolates identified as *N. gonorrhoeae* have been collected. Endocervical isolates are collected from consecutive women who present to the clinic who undergo pelvic examinations and are likely to be infected with *N. gonorrhoeae*, including those with mucopurulent cervicitis, known contacts to gonorrhea, and those with positive NAAT result at any site of interest returning for treatment until 25 endocervical isolates identified as *N. gonorrhoeae* have been collected.

Urethral, endocervical or rectal specimens suspected of being possible *N. meningitidis*<sup>#</sup> isolates are collected from men and women each month. (**optional eGISP- Part A activity**)

\*A presumptive identification of *N. gonorrhoeae* is based on the following criteria: (i) growth of typical appearing colonies with typical morphologies (e.g., small, transparent) on a selective medium such as Thayer-Martin at 35° C to 36.5° C in 5% CO<sub>2</sub>, (ii) a positive oxidase test, and (iii) the observation of Gram-negative, oxidase-positive diplococci in stained smears.

#A possible *N. meningitidis* isolate is based on the following criteria: criteria i-iii for a presumptive *N. gonorrhoeae* isolate and (iv) negative NAAT result. In the case of urethral specimen, isolates will have Gram-negative intracellular diplococci (GNID) by microscopy, but negative gonorrhea NAAT results (“discordant results”).

#### eGISP (Part B: molecular surveillance)

Corresponding NAAT samples are collected from the same patients, at the same anatomic site, and at the same clinic visit as the urethral specimens or endocervical/vaginal, rectal, or pharyngeal specimens collected through GISP and eGISP (Part A). After sentinel sites evaluate collected NAAT samples for gonococcal infection, all remnant NAAT samples corresponding to a positive GISP or eGISP gonococcal culture, regardless of NAAT result, should be submitted monthly directly to CDC for molecular testing of select known resistance- associated mutations for ceftriaxone, cefixime, azithromycin and ciprofloxacin.

### **3.1.2.1 Sentinel Site Specimen Collection: Techniques**

In order to improve the recovery of viable culture, it is recommended that two swabs be used to collect the sample at the aforementioned anatomical sites. One swab is for culture recovery by rolling the swab across the center of the modified Thayer-Martin plate. Then, with the same sampling swab, perform a continuous (zigzag) streak down and away from the inoculated-center line. Additional streaking (with a sterile inoculating loop) from the Z-line may be performed to get isolated colonies. The first swab can then be used for Gram stain procedure. The second swab may be used for NAAT analysis. In cases where two swabs cannot be obtained, it is recommended that the lone specimen-swab be processed in the following order. First, the specimen swab is used for plate inoculation by rolling the swab across the modified Thayer-Martin plate. With a sterile inoculating loop, perform a continuous (zigzag) streak down and away from the inoculated-center line. After inoculating the plate for culture, the specimen swab can be used for making a Gram stain smear. Make a smear on a glass slide using the tip-area of the specimen swab. Use this smear for Gram stain analysis. Finally, drop the specimen swab into NAAT collection/buffer tube for NAAT analysis.

### **3.1.2.2. Sentinel Site Laboratory Handling**

Isolates should be subcultured from the selective primary medium to a non-inhibitory medium, e.g., chocolate agar with 1% IsoVitaleX to obtain a pure culture of the isolate. If the subcultured isolate is not pure, serial subcultures of individual colonies must be performed until a pure culture is obtained. After 18 to 20 hours of incubation, growth from the pure culture is suspended heavily in trypticase soy broth containing 20% (v/v) glycerol and placed in a liquid nitrogen suitable cryogenic vial made from polypropylene (not glass vial); duplicate frozen cultures of each isolate are prepared. Each vial must have at least 0.5 ml of bacterial culture.

- ❖ For GISP only sentinel site isolates, all cryovials should be labeled using the GISP ID.
- ❖ For GISP/eGISP (Part A) sentinel site isolates, all cryovials should be labeled using the eGISP/SURRG specimen ID
- ❖ For eGISP (Part B) sentinel site remnant NAAT samples, all tubes should be labeled using the ID of the corresponding culture:
  - GISP ID if only participating in GISP/eGISP (Part B) or
  - eGISP/SURRG specimen ID if participating in GISP/eGISP (Part A and Part B)

(See 3.1.2.5. *Sentinel Site Assignment of Person and Specimen Identifiers*).

Isolates should be frozen to -70° C if possible. If a -70° C freezer is not available, isolates may be frozen to -20° C (freezer/dry ice chest) until shipped to the regional laboratory; isolates to be shipped must be placed in the coldest sections of the -20° C freezer (not in the door or at the front of a shelf) and should be stored in containers separate from any other frozen gonococcal cultures (including separate from duplicate frozen specimens). Whenever possible, possible *N. meningitidis* isolates should be stored at -70° C to maintain good culture viability. Please do not use Microbank (beads) for freezer stock. GISP/eGISP isolates should not be subjected to changes in temperature, which may result in loss of viability during storage. A frost-free freezer should not be used. Duplicates must be kept until the assigned ARLN Laboratory or CDC's STD Laboratory Reference & Research Branch (STDLRRB) confirms viability of isolate.

Remnant NAAT samples should be frozen to -70° C if possible. If a -70° C freezer is not available, remnant NAAT samples may be frozen to -20° C (freezer/dry ice chest) until shipped directly to CDC; remnant NAAT samples to be shipped must be placed in the coldest sections of the -20° C freezer (not in the door or at the front of a shelf) and should be stored in containers separate from frozen gonococcal cultures.

## Biosafety Recommendations

When working with unknown isolates, laboratories should always practice universal precautions while handling any material of human origin. When handling confirmed *N. meningitidis* isolates, laboratories should follow BSL-2 standard practices which include the use of a non-recirculating biological safety cabinet (BSC) and appropriate personal protective equipment (PPE), disposable closed front laboratory coat, gloves, and eye protection. When a BSC is not available, the recommended PPE includes a fit-tested N95. Laboratories should conduct a risk assessment and identify risk mitigation strategies specific to their program, procedures, and facilities.

Licensed vaccines to protect against serogroups A, B, C, Y, and W are available. There are no licensed vaccines available for non-groupable *N. meningitidis*.

### 3.1.2.3. Sentinel Site Laboratory Isolate Packaging and Shipping

Isolate (GISP and eGISP Part A) and remnant NAAT (eGISP Part B) shipments should be packaged and sent in compliance with International Air Transport Association's (IATA) "Category B", the regulatory practices followed by FedEx, ARLN's and CDC's contracted transport carrier.

Isolates (GISP and eGISP Part A) and remnant NAAT samples (eGISP Part B) should be packed in two leak-proof containers and packed in insulated Styrofoam containers with at least 10 pounds of dry ice. Shipping containers are provided by the assigned ARLN laboratory. All laboratories will return shipping containers to sites within one week of receipt.

**Shipment of *N. gonorrhoeae* isolates:** Isolates of *N. gonorrhoeae* should be batched to ship monthly. Sentinel sites should ship *N. gonorrhoeae* GISP and eGISP isolates to the assigned ARLN laboratory on a Monday, Tuesday, or Wednesday only. They should ship no later than the first Monday of the month following the month of isolation of pure colonies and receipt of NAAT results. Isolates should not accumulate for more than one month and then be shipped together because this prevents the ARLN laboratory from completing the susceptibility testing on schedule. For all *N. gonorrhoeae* isolate transfers, a shipping manifest should be uploaded electronically for transmission to the ARLN, a hard copy of the shipping manifest should be placed in the shipping container, and the ARLN POC should be notified by email in advance to shipping of isolates. (See 3.1.2.4. *Sentinel Site Laboratory Manifest Preparation and Submission*).

Isolates are shipped at no cost to the grantee using the ARLN FedEx account. ARLN labs should coordinate shipments with submitting sites using their own established shipment management protocols (e.g., providing pre-paid shipping labels or a username and password to book shipments). Submitting sites must coordinate with their ARLN laboratory POC to obtain instructions for shipping. (See Chapter 6: *Points of Contact Information*.)

**Shipment of possible *N. meningitidis* isolates (Optional eGISP Part A activity):** Isolates of possible *N. meningitidis* should be batched to ship monthly. Sentinel sites should ship possible *N. meningitidis* eGISP isolates to the STDLRRB at CDC on a Monday, Tuesday or Wednesday only. Avoid shipping specimens the day before or on holidays, including federal holidays. A *N. meningitidis* shipping manifest should be uploaded electronically for transmission to STDLRRB, a hard copy of the shipping manifest should be placed in the shipping container, and the STDLRRB POC should be notified by email in advance of shipping of isolates. (See 3.1.2.4. *Sentinel Site Laboratory Manifest Preparation and Submission*). A hard copy of the shipping manifest should be placed in the shipping container, and the *N. meningitidis* POCs should be notified by email in advance to shipping of isolates. (See 3.1.2.4. *Sentinel Site Laboratory Manifest Preparation and Submission*). If the NAAT sample for gonorrhea is negative and the isolate does not demonstrate bacterial growth consistent with *Neisseria* spp., the isolate should not be shipped to CDC. Isolates are shipped at no cost to the grantee using the ARLN FedEx account used to ship *N. gonorrhoeae* GISP and eGISP isolates.

**Shipment of remnant NAAT samples (eGISP Part B only):** Remnant NAAT samples of corresponding *N. gonorrhoeae* isolates should be batched to ship monthly. Sentinel sites should ship all remnant NAAT samples corresponding to *N. gonorrhoeae* GISP and eGISP (Part A) isolates to the STDLRRB at CDC on a Monday, Tuesday or Wednesday only. Avoid shipping remnant NAAT samples the day before or on holidays, including

federal holidays. The shipping manifest used for the submission of gonococcal cultures can be used for the submission of remnant NAAT samples, as long as the sample IDs on the manifest correspond to the sample IDs included on the remnant NAAT sample tubes. A hard copy of the shipping manifest should be placed in the shipping container with the remnant NAAT samples, and the CDC STDLRRB POCs should be notified by email in advance of shipping of remnant NAAT samples. (See *3.1.2.4. Sentinel Site Laboratory Manifest Preparation and Submission*). If the corresponding gonococcal isolate is sent to the ARLN, the remnant NAAT sample, regardless of gonococcal NAAT result, should be shipped to CDC. The cost of shipping the remnant NAAT samples to STDLRRB are covered by the sentinel site using eGISP (Part B) funding awards.

### **3.1.2.4. Sentinel Site Laboratory Manifest Preparation and Submission**

As the ARLN laboratories conduct susceptibility testing of *N. gonorrhoeae* isolates from multiple projects (e.g., SURRG, GISP, and eGISP), a single manifest format is used (See Figure 1. GISP/eGISP Manifest for *N. gonorrhoeae*). For sites participating in eGISP (Part B), this same manifest can be used for the shipment of remnant NAAT samples to CDC, as long as the specimen IDs listed on the manifest are the same as the specimen IDs included on the remnant NAAT tubes. Sites should review the Manifest for *N. gonorrhoeae* prior to submission to make sure all listed gonococcal samples are associated with a remnant NAAT sample.. A second manifest format is used for shipping *N. meningitidis* isolates as part of the optional eGISP (Part A) activities (Figure 2. eGISP Manifest for *N. meningitidis*).

The manifests identify the variables that are required to be provided with the isolate's shipment. Required variables vary by project; sentinel sites participating in GISP only or GISP/eGISP (Part B) only are required to complete the sections of the manifest under the label "GISP sites only" and sentinel sites participating in both GISP/eGISP (Part A) or GISP/eGISP (Part A and Part B) are required to complete the sections of the manifest under the label "GISP & eGISP sites" (See Table 3. *Manifest Data Elements* and Table 4. *Facility Location Codes*). Printed copies of the completed manifests should be included with each isolate and remnant NAAT sample shipment.

The table below summarizes the data elements required to be included on all shipping manifests (paper and electronic) submitted for GISP and eGISP *N. gonorrhoeae* isolates, GISP and eGISP remnant NAAT samples, as well as the data elements required to be included for eGISP *N. meningitidis* isolates (**optional eGISP activity**).

Table 3. Manifest Data Elements

Required for	Data Element Name	Data Element Description
eGISP (Part A) sites	eGISP/SURRG specimen ID*	Site-created ID consisting of 3 letter sentinel site code (coded, see below) + local public health lab accession number, with no spaces or hyphens, e.g. DEN2372001
eGISP (Part A) sites	Patient ID	Patient identifier generated at the clinic/lab that is not a medical record number and does not contain personally identifiable information
eGISP (Part A) sites	Specimen source	Anatomic site of specimen; 2 characters max U = Urethral V = Vaginal E = Endocervical R = Rectal P = Pharyngeal NC = Not Captured
eGISP (Part A) sites	Specimen collection date	Date of specimen collection; 10 characters (MM/DD/YYYY)
eGISP (Part A) sites	Gender	Patient gender; numeric, 1 digit code 1=Male 2=Female 3=Trans Male 4=Trans Female 5=Non-binary/Trans Other 9=Unknown
eGISP (Part A) sites <i>(participating in optional Nm activity)</i>	Possible Nm	Yes= isolate may be <i>N. meningitidis</i> No= Isolate has been positively identified as <i>N. gonorrhoeae</i>
eGISP (Part A) sites	Age	Patient age (in years; no decimals; 3 digits max)
All GISP/eGISP sites	Patient date of Birth	Patient date of birth; 10 characters (MM/DD/YYYY) Not transmitted to CDC
All GISP/eGISP sites	Facility location	Clinic where specimen was collected (see Table 4. Facility Location Codes)
All GISP/eGISP sites	GISP specimen ID	For all GISP sites, monthly submission specimen number consisting of sentinel site code + YRMO (YYYYMM of isolate submission date) + isolate number (01 through 50), separated by hyphens e.g., NYC-202103-04

\*Although eGISP (Part A) sites are not part of SURRG, to minimize the number of identifiers on the shipping manifest and in the ARLN laboratory information system, one specimen ID type (eGISP/SURRG ID) is used for both eGISP (Part A) and SURRG activities

Table 4. Facility Location Codes

Facility State	Submitting Facility	Facility Code
NM	Albuquerque	ALB-01
AK	Anchorage	ANC-01
MD	Baltimore	BAL-01
AL	Birmingham	BHM-01
NY	Buffalo	BUF-01
IL	Chicago (Lakeview)	CHI-01
IL	Chicago (South Austin)	CHI-03
OH	Cleveland	CLE-01
OH	Columbus	COL-01
TX	Dallas	DAL-01
CO	Denver	DEN-01
NC	Greensboro	GRB-01
HI	Honolulu	HON-01
IN	Indianapolis	IND-01
MO	Kansas City	KCY-01
NV	Las Vegas	LVG-01
CA	Los Angeles	LA1-01
CA	Los Angeles	LA2-01
WI	Milwaukee	MIL-01
MN	Minneapolis	MIN-01
LA	New Orleans (Delgado)	NOR-01
LA	New Orleans (CrescentCare)	NOR-02
NY	New York City	NYC-01
CA	Orange County	ORA-01
PA	Philadelphia	PHI-01
AZ	Phoenix	PHX-01
PA	Pittsburgh	PIT-01
MI	Pontiac	PON-01
OR	Portland	POR-01
CA	San Diego	SDG-01
CA	San Francisco	SFO-01
WA	Seattle	SEA-01
HI	Tripler Army Medical Center	TRP-01
DC	Washington D.C.	WDC-01

**For *N. gonorrhoeae* isolates:** A printed copy of the completed *N. gonorrhoeae* GISP/eGISP shipping manifest should be included with each isolate shipment. Participating eGISP (Part B) sites should edit the manifest to reflect any missing or unavailable remnant NAAT samples prior to printing a hard copy and including it in the remnant NAAT samples shipment box. An electronic version of the manifest should be submitted to the ARLN or CDC (eGISP Part B remnant NAAT samples) lab through the file transfer portal (FTP) site.

Figure 1. GISP/eGISP Manifest for *N. gonorrhoeae*

GISP/eGISP/SURRG Isolate Shipping Manifest											
<b>Instructions:</b> - This form should be completed for all isolate shipments to your assigned ARLN laboratory & a printed copy should be included with your shipment. - Variables are specific for each project, please follow the guidance below and ensure variables are formatted correctly (see examples provided). - If more than 50 isolates are sent in a shipment, please add additional rows to spreadsheet prior to completion.											
Clinical site(s):			Ship Date:		# of isolates in shipment:						
					GISP only sites						
					GISP & eGISP sites						
					SURRG only sites						
					GISP & SURRG sites						
S var**	Jurisdiction Public Health Lab	SURRG/eGISP Specimen ID	Patient ID	Specimen Source	Specimen Collection date	Gender	Possible Nm*	AGE	Patient DOB	Facility location	GISP ID
	Jurisdiction_PHL	SURRG_Spec_ID	Patient_ID	Specimen_type	Specimen_collection_date	Patient_Gender	N/A	Patient_age	Patient_DOB_B	GC_facility_code	GISP_Spec_ID
Ex.	SFL	SFOCC170107918	285962	U	8/27/2017	1	No	20	8/1/1997	SFO-01	SFO-201708-09
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											

\*Note: this manifest can be used for the submission and shipment of eGISP (Part B) remnant NAAT samples.

- For GISP only sites: please complete manifest as "GISP only sites"
- For GISP/eGISP (Part B only) sites: please complete manifest as "GISP only sites"
- For GISP/eGISP (Part A) sites: please complete manifest as "GISP & eGISP sites"
- For GISP/eGISP (Part A and Part B) sites: please complete manifest as "GISP & eGISP sites"

**For possible *N. meningitidis* isolates (Optional: eGISP):** A printed copy of the completed *N. meningitidis* eGISP shipping manifest should be included with each *N. meningitidis* isolate shipment. An electronic version of the manifest should be submitted to CDC through the file transfer portal (FTP) site.

Figure 2. eGISP Manifest for *N. meningitidis*

eGISP Shipping Manifest for Possible <i>Neisseria meningitidis</i> Isolates								
<b>Instructions:</b> - This form should be completed for all possible Nm isolate shipments to the CDC Bacterial Meningitis Lab & a printed copy should be included with your shipment. - Please follow the guidance below and ensure variables are formatted correctly (see examples provided). - If more than 50 isolates are sent in a shipment, please add additional rows to spreadsheet prior to completion.								
Clinical site(s):			Ship Date:					
# of isolates in this shipment								
Example	SURRG/eGISP Specimen ID	Patient ID	Specimen Source	Specimen Collection date	AGE	Gender	Possible Nm	Comments
	COLCC170107918	285962	U	8/27/2017	20	1	Yes	
1							Yes	
2							Yes	
3							Yes	
4							Yes	
5							Yes	
6							Yes	
7							Yes	
8							Yes	
9							Yes	
10							Yes	
11							Yes	
12							Yes	
13							Yes	
14							Yes	
15							Yes	

### **3.1.2.4.1 Submission and Naming of Shipping Manifests**

The manifest should be electronically submitted to the ARLN laboratory or CDC STDLRRB using the secure FTP on or before the day the corresponding isolates are shipped [see Appendix: *Instructions for Use of CDC Private File Transfer Portal (FTP)*].

**N. gonorrhoeae:** When the manifest is uploaded to the FTP, the submitting site should notify the ARLN laboratory POC via email (See Chapter 6: Contact Information and Mailing Addresses) to inform them that a manifest has been posted in the FTP, and when to expect the corresponding shipment of isolates to arrive.

The naming convention is sentinel site code\_month\_year\_project\_Routine (See Table 5. Sentinel Site Codes).

GISP only example: PHI\_05\_2021\_GISP\_Routine

GISP/eGISP (Part A) example: NOR\_05\_2022\_eGISP\_Routine

\*Note: GISP/eGISP (Part B only) sites should use the GISP only naming convention. GISP/ eGISP (Part A and Part B) sites should use the GISP/eGISP (Part A) naming convention.

**N. meningitidis (Optional eGISP activity):** When the manifest is uploaded to the FTP, the submitting site should notify the *N.meningitidis* POC via email to inform them that a manifest has been posted in the FTP, and when to expect the corresponding shipment of isolates to arrive.

<b><i>N. meningitidis Points of Contact</i></b>	Dr. Sancta St. Cyr  Dr. Cau Pham	<a href="mailto:oew3@cdc.gov">oew3@cdc.gov</a>  <a href="mailto:whi4@cdc.gov">whi4@cdc.gov</a>	404-718-5447  404-718-5642
---	--	--	----------------------------------

The naming convention is sentinel site code\_month\_year\_Nm (See Table 5. Sentinel Site Codes).

*N. meningitidis* example: COL\_09\_2021\_Nm

### **3.1.2.5. Sentinel Site Assignment of Person and Specimen Identifiers**

#### **GISP (culture-based surveillance)**

For sentinel sites participating in GISP only activities, isolates from the first 25 male patients with gonococcal urethritis are considered “GISP isolates” and are assigned sequential identifiers for each month. Each identifier, known as a GISP ID, is composed of a three-letter designation for the sentinel site (See Table 5. *Sentinel Site Codes*), followed by a six-digit number indicating the year and month of isolate collection (yyyymm), and a two-digit number in the sequence from 01 through 25 or higher. Hyphens should be used to separate the sentinel site code and numerical sequences. For example, the 20th isolate selected in January 2022 in Columbus will be given the number COL-202201-20. The GISP ID must be maintained for at least the first 25 male gonococcal urethritis isolates.

#### **eGISP (Part A- culture-based surveillance)**

In addition to GISP activities, sentinel sites participating in eGISP (Part A) activities also collect isolates from multiple anatomic sites from both male and female patients understanding patients may have multiple anatomic sites of infections. Therefore, an isolate specific specimen ID and a unique patient identifier are required for eGISP isolates. For all eGISP (Part A) isolates collected, including isolates that are identified as possible *N.*

*meningitidis*, eGISP (Part A) sites should assign and maintain an eGISP/SURRG specimen ID<sup>1</sup>, constructed using the 3-letter sentinel site code + local public health laboratory accession number (no hyphens or spaces). See Table 5. *Sentinel Site Codes*. For sentinel sites who are funded for both GISP and eGISP (Part A) activities, isolates from the first 25 male patients with gonococcal urethritis are considered “GISP isolates” while all urethral isolates are considered “eGISP isolates”. All isolates require an eGISP/SURRG specimen ID. Therefore, eGISP sites that are also GISP sites should assign and maintain a GISP ID locally constructed by concatenating the variables of sentinel site code+year month+GISP isolate ID number, separated by hyphen, (e.g., COL-202103-07) in addition to the eGISP ID. See Table 5. *Sentinel Site Codes*. The GISP ID must be maintained for at least the first 25 male gonococcal urethritis isolates.

Table 5. Sentinel Site Codes

Three letter code for use in constructing eGISP/SURRG ID and GISP ID	
Sentinel Site	Sentinel Site Code
Albuquerque	ALB
Anchorage	ANC
Baltimore	BAL
Birmingham	BHM
Buffalo	BUF
Chicago	CHI
Cleveland	CLE
Columbus	COL
Dallas	DAL
Denver	DEN
Greensboro	GRB
Honolulu	HON
Indianapolis	IND
Kansas City	KCY
Las Vegas	LVG
Los Angeles	LA1, LA2
Milwaukee	MIL
Minneapolis	MIN
New Orleans	NOR
New York City	NYC
Orange County	ORA
Philadelphia	PHI
Phoenix	PHX
Pittsburgh	PIT
Pontiac	PON
Portland	POR
San Diego	SDG

<sup>1</sup> Although eGISP sites are not part of SURRG, to minimize the number of identifiers on the shipping manifest and in the ARLN laboratory information system, one specimen ID type (eGISP/SURRG ID) is used for both eGISP (Part A) and SURRG activities.

### Three letter code for use in constructing eGISP/SURRG ID and GISP ID

Sentinel Site	Sentinel Site Code
San Francisco	SFO
Seattle	SEA
Tripler Army Medical Center	TRP
Washington D.C.	WDC

An eGISP patient identifier should be assigned for each patient from which an isolate is collected. The patient identifier must be unique within the jurisdiction, up to 18 characters in length, and remain consistent across visits and the life cycle of eGISP (Part A). Sentinel sites may use unique patient IDs from existing disease surveillance systems or some other uniquely constructed patient ID, however the eGISP patient ID cannot contain personally identifiable information [PII; date of birth (DOB), Social Security Number (SSN), medical record number (MRN or EHR number)]. The sentinel site eGISP POC or designated data manager is responsible for generating and maintaining the patient IDs. Note: the eGISP patient ID (“Patient ID”) is used to relate associated specimen(s) to each patient in the data transmission (e.g. shipping manifest) to the ARLN or CDC (e.g., link a patient’s laboratory results to their epidemiologic data). This ID should be included in both data transmissions: on the manifest to the assigned ARLN laboratory or CDC and as part of the clinical/demographic data sent directly to CDC.

Within eGISP (Part A), the unique patient IDs and eGISP/SURRG specimen IDs allow merging of clinical and demographic data with antimicrobial susceptibility test (AST) results from the ARLN laboratory and other laboratory sources. As described above, all eGISP (Part A) cryovials should be labeled using the eGISP/SURRG specimen ID. See *3.1.2.2. Sentinel Site Laboratory Handling*.

#### eGISP (Part B- molecular surveillance)

For sentinel sites participating in eGISP (Part B) activities, the identifier used for remnant NAAT samples should be based on the culture-based surveillance activity the sentinel site participates in. The remnant NAAT specimen identifier should have the same identifier as the corresponding gonococcal culture. Sites that participate in only GISP culture-based surveillance should use the same GISP ID on its gonococcal isolates and its remnant NAAT samples. Sites that participate in eGISP (Part A) culture-based surveillance should use the same eGISP/SURRG specimen ID on its gonococcal isolates and remnant NAAT samples. (*See above for descriptions on how to create GISP IDs and eGISP/SURRG IDs*). Participating sites should remove all personally identifiable information (PII) labeling from the remnant NAAT tubes prior to submission to CDC.

#### **3.1.2.5. Sentinel Site Data management**

Each sentinel site laboratory should maintain a monthly log of GISP and eGISP/SURRG identification numbers and the corresponding patient name or identification number. This log is for local use only and is not to be shared with the ARLN laboratory or CDC. This information must be routinely shared with the sentinel site staff person who is responsible for abstracting clinical/demographic data on GISP and eGISP (Part A) patients. So that data can be properly merged at CDC, the GISP ID and eGISP/SURRG specimen ID of an individual isolate on the manifest must match the GISP ID and eGISP/SURRG specimen ID number of the isolate in the clinical/demographic data. For sites participating in eGISP (Part B), the GISP ID and eGISP/SURRG specimen ID of an individual isolate on the manifest must match the GISP ID and eGISP/SURRG specimen ID number of the tube of the remnant NAAT sample. Data collected through GISP and eGISP (Part A) culture-based surveillance will be matched to laboratory data from remnant NAAT samples at CDC. Additional submission of data is not necessary for eGISP (Part B).

### **3.1.3. Sentinel Site Clinic or Program Activities**

#### **3.1.3.1 Retrieval of AST Results**

The ARLN provides CDC and the sentinel site the antimicrobial susceptibility testing (AST) results for *N. gonorrhoeae*. CDC uses the results to monitor *N. gonorrhoeae* antimicrobial susceptibility trends nationally and inform treatment recommendations. Sentinel sites are encouraged to use site-specific data to describe the epidemiology of *N. gonorrhoeae* in their jurisdictions. AST results for isolates collected through GISP and eGISP should not be used for patient management.

The ARLN notifies the sentinel site POC anytime AST agar dilution results for isolates from that grantee are posted by the ARLN into the FTP portal. Results for isolates that are confirmed to be an “Alert”\* via agar dilution should be posted within 24 hours of the results being finalized. Batched AST results, which include results for Alert and non-Alert isolates, should be posted within 4 weeks of submission. The sentinel site POC should access reports and share locally as needed.

#### **\*Alert MIC Criteria**

**Ceftriaxone MIC  $\geq$  0.125  $\mu\text{g/ml}$**

**Cefixime MIC  $\geq$  0.25  $\mu\text{g/ml}$**

**Azithromycin MIC  $\geq$  2.0  $\mu\text{g/ml}$**

The ARLN does not conduct AST for *N. meningitidis*; AST of *N. meningitidis* isolates is performed by CDC laboratories based on available funding and resources.

#### **3.1.3.2 Retrieval of Molecular Marker Results**

The CDC provides the sentinel sites with reports of the aggregate resistance-associated mutation results for select antimicrobials for each remnant NAAT sample associated with a positive *N. gonorrhoeae* culture collected through GISP and eGISP (Part A). CDC will use the results to describe the prevalence of genetic mutations circulating in gonorrhea in the US, to monitor *N. gonorrhoeae* antimicrobial resistance nationally, and to inform national treatment recommendations. Sentinel sites are encouraged to use site-specific data to describe the epidemiology of AMR *N. gonorrhoeae* in their jurisdictions. Results from molecular testing performed on remnant NAAT samples collected through eGISP (Part B) should not be used for patient/clinical management.

The CDC notifies the sentinel site POC anytime molecular testing results from remnant NAAT samples are posted by the CDC into the FTP portal. Reports of aggregate, site-specific molecular testing results (indicating number of AR molecular marker assay positive specimens) should be posted within 3 months of remnant NAAT sample submission. The sentinel site POC should access reports and share locally as needed..

#### **3.1.3.3. Reporting Clinical and Demographic Data**

Clinical and demographic data should be submitted for each patient from whom a GISP and/or eGISP (Part A) isolate is submitted. For GISP sentinel sites, isolates from the first 25 male patients with gonococcal urethritis are considered “GISP isolates” and are assigned a GISP ID. For combined GISP/eGISP (Part A) sentinel sites, all isolates are assigned an eGISP/SURRG specimen ID (See *3.1.2.5. Sentinel Site Assignment of Person and Specimen Identifiers*). Data may be obtained through review of medical records by clinic staff. Line-listed de-identified clinical and demographic data elements associated with each isolate are collected by the sentinel site. eGISP (Part A) sentinel sites assign a unique identifier to the patient (“Patient ID”), so as to enable identification of multiple isolates that are collected from the same patient and include this identifier with the line-listed transmitted data. Additional clinical and demographic data are not required for eGISP (Part B) activities.

Clinical and demographic data should be sent to CDC monthly as an Excel spreadsheet (.xls data file). Sites are provided with the Excel template and data dictionary. Data should be received at CDC *no more than four weeks* after the end of the month in which the corresponding isolates were provided.

The GISP/eGISP Clinical/Demographics Data Elements Table (See Chapter 5. *Clinical/ Demographic Data Elements*) provides detailed descriptions of the requested data elements and instructions on correct coding of responses. The following is a concise list of the requested clinical and demographic data elements collected:

- Sentinel site code
- Clinic ID (for those sentinel sites submitting isolates from more than one clinic)
- Patient ID (**only required for eGISP- Part A sentinel sites**)
- eGISP/SURRG ID (**only required for eGISP- Part A sentinel sites**)
- GISP ID
- Patient gender
- Ethnicity
- Race
- Date of clinic visit
- Age
- Gender of sex partner
- Anatomic site of isolate collection (**only required for eGISP- Part A sentinel sites**)
- Nucleic acid amplification test (NAAT) result (**only required for eGISP- Part A sentinel sites**)
- Presence of symptoms
- Previous history of gonorrhea
- Number of previous confirmed episodes of gonorrhea in past year
- HIV status at time of clinic visit for gonorrhea (including results of HIV testing at the time of the clinic visit)
- Travel outside the United States during the previous 60 days
- History of giving or receiving drugs/money for sex in the previous 12 months
- Any antibiotic use during the previous 60 days
- History of injection drug use in the previous 12 months
- History of non-injection recreational drug use (excluding alcohol) in the previous 12 months
- Primary treatment for gonorrhea (such as ceftriaxone)
- Secondary treatment for gonorrhea (as of December 2020, dual therapy is no longer recommended; however, some alternative regimens may use a secondary drug as treatment)
- Meningococcal vaccination history (**only required for eGISP- Part A sentinel sites**)
- Possible *Neisseria meningitidis* isolate (**only required for eGISP- Part A sentinel sites** participating in the optional activity)

### **3.1.3.4. Submission of Clinical and Demographic data to CDC**

The clinical and demographic data file (.xls) should be securely transmitted to CDC each month. This data should only be transmitted to CDC following the Secure Access Management Service (SAMS) protocol. A completed GISP/eGISP Data Submission Memo should accompany each submitted clinical and demographic data file. Each clinic is allowed to designate 2 users who will receive SAMS registration/credentials. CDC will formally acknowledge all data transmissions received and the clinic submitter will be notified of this acknowledgement via e-mail.

The naming convention of the .xls clinical/demographic data file is *sentinel site code\_month\_year\_Epi* (See Table 5. *Sentinel Site Codes*).

GISP only example: PHI\_05\_2021\_GISP\_Epi.xls

GISP/eGISP (Part A) example: NOR\_05\_2022\_eGISP\_Epi.xls

### **3.1.3.5. Annual Process Measures Reporting**

As described in the Epidemiology and Laboratory Capacity (ELC) Program (CDC-RFA-CK19-1904), sentinel sites are expected to monitor and report on process measures to document progress towards achieving GISP and eGISP project outcomes. The data should be submitted to CDC as part of Progress Reports and Performance Measures Reports.

**At a minimum, GISP awardees are expected to monitor and report on the following measures:**

- Number of all men attending the participating clinic that tested for gonorrhea at the urethral site with negative results (all men tested by STD clinic with negative gonococcal urethral results)
- Number of all cases of gonococcal urethritis diagnosed in men attending the participating clinic (all men tested by clinic with positive gonococcal urethral results)
- Number and percentage of urethral gonococcal isolates submitted to the regional laboratory as part of GISP (all gonorrhea isolates submitted for GISP)
- Number and percentage of submitted isolates that were found by the GISP regional laboratory to be non-viable or contaminated (all non-viable or contaminated GISP samples)
- Percentage of monthly isolate batches that were shipped to the GISP regional laboratory within one week after the end of monthly collection (timeliness of all shipments)
- Percentage of monthly demographic/clinical data transmissions that were submitted to CDC within one month of the completion of specimen collection (completeness and timeliness of epidemiological data)
- Percentage of collected isolates for which the following data elements are reported: (a) age, (b) gender of sex partner/sexual orientation, (c) HIV status, (c) antibiotic use, and (d) treatment

In addition, awardees should describe their plans to address challenges faced in enrollment, specimen quality and viability, timeliness of specimen or data transmission, and data completeness.

**At a minimum, eGISP (Part A) awardees are expected to monitor and report on the following measures:**

- Number of men who present to the affiliated STD clinic(s) with urethritis and the number of men who report sexual exposure at the oropharynx and/or rectum. Of these men:
  - By anatomic site: number/proportion of men that 1) have specimens collected and 2) specimens that are tested by Gram stain, culture and/or NAAT
  - By anatomic site: number/percentage of specimens that demonstrate typical growth by culture (i.e., have positive cultures)
- Number of women who undergo a pelvic examination at the affiliated STD specialty clinic(s) and the number of women who report sexual exposure at the oropharynx and/or rectum. Of these:
  - By anatomic site: number/proportion of women that 1) have specimens collected and 2) have specimens tested by Gram stain, culture, and/or NAAT
  - By anatomic site: number/percentage of specimens that demonstrate typical growth by culture (i.e., have positive cultures)
- Number/percentage of collected isolates for which complete epidemiological data are reported to CDC
- By gender and anatomic site (i.e., urethral, oropharynx, rectum, and cervix):
  - Number/percentage of isolates that demonstrate typical growth by culture (i.e., have positive cultures)
  - Number/percentage of isolates that are identified with discordant laboratory results (i.e., GNID by Gram stain/positive cultures and negative gonorrhea NAAT)
  - Number/percentage of isolates for which requested epidemiological data are reported to CDC

**At a minimum, eGISP (Part B) awardees are expected to monitor the following measure:**

- Number of remnant NAAT samples submitted directly to CDC compared to total number of gonococcal isolates submitted to GISP regional laboratory

- Number of submitted remnant NAATs with *N. gonorrhoeae* positive, negative, or indeterminant/equivocal results

## 3.2. ARLN Laboratories

The Antibiotic Resistance Lab Network (ARLN) regional public health laboratories that are funded for *Neisseria* activities are responsible for bacterial identification, determining  $\beta$ -lactamase activity, and performing antimicrobial susceptibility testing (AST) on all GISP and eGISP *N. gonorrhoeae* isolates received from the sentinel sites. They are also responsible for reporting AST results to CDC and sentinel sites and shipping selected isolates to CDC. ARLN also facilitates the transfer of possible *N. meningitidis* isolates to CDC. The current ARLN laboratories performing *N. gonorrhoeae* testing are Washington State Public Health laboratory, Tennessee State Public Health Laboratory, Maryland Public Health Laboratory, and Utah Public Health Laboratory. (See Chapter 6. *Contact Information and Mailing Addresses*).

### 3.2.1. Assignment of GISP and eGISP sentinel sites to ARLN laboratory

Table 6. ARLN assignments for GISP and eGISP (Part A)\*

ARLN Laboratory	GISP only sites	GISP/eGISP (Part A) sites
Utah Public Health Laboratory	Albuquerque; Dallas; Denver; Kansas City	Las Vegas; Phoenix
Washington State Public Health Laboratory	Anchorage; Honolulu; Los Angeles; Portland; San Francisco; Seattle; Tripler Army	Orange County; San Diego
Tennessee State Public Health Laboratory	Birmingham; Chicago; Greensboro; Indianapolis; Kansas City; Milwaukee; Minneapolis; Pontiac	New Orleans
Maryland Public Health Laboratory	Baltimore; Buffalo; Cleveland; New York City; Pittsburgh; Washington D.C.	Columbus; Philadelphia

\* Activities under eGISP (Part B) do not include testing by the ARLNs. ARLN laboratory assignments are based on GISP and eGISP (Part A) culture-based project participation and are subject to change.

### 3.2.2. *Neisseria* Cultures Identification

*Neisseria gonorrhoeae* isolates must be identified by the ARLN using either a combination of biochemical tests and enzymatic reactivity assays (e.g., API NH and RapID NH), immunological assays (e.g., Phadebact), or possibly matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS). See Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 6, Section 7: “*Neisseria* Species Identification” for more information on this topic.

### 3.2.3. Beta ( $\beta$ )-Lactamase Activity Assay

The Nitrocefin test will be used to assess the isolates for  $\beta$ -lactamase activity. Two test options are listed below:

- A drop of Nitrocefin can be added directly to an isolated colony on a plate containing an overnight culture.
- A slide, broth, or filter paper can also be used to mix an isolated colony with Nitrocefin to determine the presence of  $\beta$ -lactamase.

See Supplement: A Collection of Protocols and Expectations for the CDC *Neisseria gonorrhoeae* Regional Antimicrobial Resistance Lab Network Chapter 6, Section 10: “ $\beta$ -lactamase Assay” for detailed description of the assay.

### 3.2.4. Antimicrobial Susceptibility Testing (AST)

#### *Agar-dilution AST Method*

Agar dilution is the gold-standard AST method for *N. gonorrhoeae*. It will be the only method utilized for susceptibility testing of *N. gonorrhoeae* at ARLN laboratories. See Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 6, Section 9: “Agar-dilution Antimicrobial Susceptibility Testing” for detailed information on how to perform agar dilution AST.

#### AST Growth Medium

Difco gonococcal (GC) medium base supplemented with 1% IsoVitaleX will be used as growth medium for *N. gonorrhoeae* AST assay. The dehydrated GC medium base will be reconstituted and steam sterilized in an autoclave. IsoVitaleX and the appropriate antimicrobial agent dilution are added to the molten GC medium base, equilibrated to 52-55 °C in a water bath, before being dispensed into plastic petri plates.

#### Antibiotics and Antibiotic Concentrations

All *N. gonorrhoeae* isolates will be tested for susceptibility to azithromycin, ceftriaxone, cefixime, ciprofloxacin, gentamicin, penicillin, and tetracycline by agar dilution. It is recommended that all isolates must be tested against the antibiotic concentrations as listed in Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 5, Section 6.2.3.:“Antibiotics and Antibiotic Concentrations.”

#### Isolates with Alert Value MICs

Isolates will be categorized as “Quick-Send Alert”, “Alert”, or “Susceptible” based on azithromycin, ceftriaxone, and cefixime MICs for each isolate.

#### “Alert” Values and “Quick-Send Alert” Values

Antimicrobial Agent	“Alert” Value	“Quick-Send Alert” Value
Ceftriaxone	MIC $\geq$ 0.125 $\mu\text{g}/\text{ml}$	MIC $\geq$ 0.5 $\mu\text{g}/\text{ml}$
Cefixime	MIC $\geq$ 0.25 $\mu\text{g}/\text{ml}$	MIC $\geq$ 1.0 $\mu\text{g}/\text{ml}$
Azithromycin	MIC $\geq$ 2.0 $\mu\text{g}/\text{ml}$	MIC $\geq$ 16 $\mu\text{g}/\text{ml}$

Any *N. gonorrhoeae* isolates from GISP and eGISP identified as Quick-Send must be shipped to the CDC within one working day after reporting of Quick-Send Alert isolate. Any *N. gonorrhoeae* isolates from GISP and eGISP identified as Alert can be batched and shipped to the CDC on a quarterly basis. Non-alert isolates that have not

been submitted to the CDC as Quick-Send, Alerts, Whole Genome Sequencing, or as a special request must be transferred to the CDC on a semi-annual basis.

#### Reporting Frequency for Aggregate AST Data

Aggregate AST reports must be sent to sentinel sites and CDC on a monthly basis. The report should be sent to sentinel sites within 4 weeks of receiving the isolates. Aggregate AST reports must be sent using the FTP site. The ARLN laboratories should notify the sentinel sites POC via email that results are available in the FTP folder. See Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 8, Subchapter II, Section 3: “Agar-Dilution AST Result Reporting” for more information on this topic.

#### Reporting Alert MICs

Alert MICs will be reported to the submitting sentinel site and the CDC. Alert MICs must be reported expeditiously, or within 24 hours, after detection through AST. Confirmed Alert MIC results must also be reported within 24 hours after confirmation. Do not resubmit the result if the Alert MIC is not reproduced upon retesting. ARLN laboratories will inform submitting sentinel sites of confirmed Alert results through the FTP site. The ARLN laboratories must email the submitting sentinel site POC to inform that Alert results have been placed in the FTP site. These results should be provided in an Excel file format and any alert values should be highlighted. See Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 8, Subchapter II, Section 3: “Agar-Dilution AST Result Reporting” for more information on this topic.

### **3.2.5. Whole Genome Sequencing (WGS)**

Each month, the ARLN laboratories are required to perform whole genome sequencing on a subset of the *N. gonorrhoeae* isolates that they received from the GISP and eGISP sentinel sites. Isolates are selected for whole genome sequencing based on criteria detailed in See Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 8, Subchapter V: “Guidance for Whole Genomic Sequencing of *Neisseria gonorrhoeae*” for additional information.

### **3.2.6. Quality Control (QC)**

Three QC strains will be tested with each AST run. One strain, ATCC 49226, must be within acceptable ranges as published in the CLSI M-100 document for the data to be considered valid and reportable to CDC. Tests with out-of-range minimum inhibitory concentration (MIC) values must be repeated until the QC strain is within range. Two additional QC strains will be supplied by CDC each year. The data of all QC strains must be kept together with test isolates for each run for two years from the test date. ARLN laboratories are required to provide the AST data of QC strains upon request by the CDC.

### **3.2.7. Timeliness or Turn-Around-Time (TAT)**

It is expected that susceptibility testing, including results of QC strains, will be completed within three weeks of receipt of isolates.

### **3.2.8. Isolate Preservation**

Preservation of viable isolates is an essential laboratory practice when performing *Neisseria* spp. culturing. The preservation process ensures that the *Neisseria* isolate is available and viable for future use. With appropriate preservation conditions, *Neisseria* isolates will remain viable for decades. One common method for preserving bacterial culture is to keep the stock-culture at, or below negative 70 °C. Instructions for how to prepare freezer stock of *Neisseria* culture and maintain freezer stocks for long-term storage are provided in Supplement: *A Collection of Protocols and Expectations for the CDC Neisseria gonorrhoeae Regional Antimicrobial Resistance Lab Network*, Chapter 6, Section 8: “*Neisseria gonorrhoeae* and *N. meningitidis* Preservation.”

### **3.2.9. Consultation for Sentinel Sites**

The ARLN laboratories may need to provide technical assistance consultation to sentinel sites to improve or optimize the quality of GISP and eGISP (Part A) isolates submitted. If a problem with non-viability or contamination is recognized by the ARLN laboratory, this should be brought to the attention of the sentinel site quickly, as these problems may indicate problems with sentinel site isolate collection, handling, storage, or shipping.

## **3.3. Centers for Disease Control and Prevention**

The DSTDP Surveillance and Data Science Branch (SDSB) and STD Laboratory Reference & Research Branch (STDLRRB) perform the administrative duties and technical assistance responsibilities relating to GISP and eGISP (Part A and Part B). (See Chapter 6. *Contact Information and Mailing Addresses*)

In addition, CDC's STDLRRB is responsible for performing molecular testing of resistance-associated mutations on all eGISP (Part B) remnant NAAT samples received from participating sentinel sites. STDLRRB is also responsible for reporting molecular testing aggregate results quarterly to CDC SDSB and sentinel sites.

### **3.3.1. Molecular Testing for Antimicrobial Resistance-Associated Mutations**

Culture-based gonococcal susceptibility testing methods using agar dilution have historically been used in national surveillance programs like GISP. This method of susceptibility testing allows for the phenotypic identification of recognized and novel resistance patterns. Molecular testing on culture-independent samples can be used to follow trends of known and concerning resistance markers over time. Additionally, molecular testing is a faster and less expensive technique than WGS and doesn't require gonococcal isolates. This method cannot determine novel genetic mutations and cannot replace current culture-based surveillance, but it could provide an opportunity to better characterize circulating resistance patterns.

Nucleic acid amplification testing (NAAT), a culture-independent testing method, is the most common method of diagnosing gonorrhea in the US and is a highly sensitive and specific method. Using knowledge of known mutations that are associated with antimicrobial resistance in *N. gonorrhoeae*, molecular testing can be used to identify the presence or absence of mutations at specific genetic loci resulting in antimicrobial resistance.

#### Molecular Testing Method:

After the initial gonorrhea diagnosis, participating eGISP (Part B) sentinel sites store and then ship monthly the remnant NAAT samples to STDLRRB for additional testing and analyses. Once received at STDLRRB, remnant NAAT samples undergo a process of 1) genetic material extraction from the NAAT buffer/tubes, 2) DNA quality control assays, 3) PCR amplification of areas of interest (specific loci within the 23S rRNA, penA, and gyrA genes), and 4) identification of specific known resistance-associated genetic mutations for azithromycin (23S rRNA), ceftriaxone (mosaic penA), cefixime (mosaic penA), and ciprofloxacin (gyrA). All submitted remnant NAAT samples are evaluated, regardless of local NAAT results, for the presence or absence of specific known genetic mutations associated with resistance to azithromycin, ceftriaxone, cefixime, and ciprofloxacin. Additional molecular testing details are available upon request.

#### Reporting Frequency for Molecular Testing Data:

A site-specific aggregate report of molecular testing results is sent to each participating eGISP (Part B) sentinel site on a quarterly basis. The report should be sent to sentinel sites within 3 months of receiving the remnant NAAT samples. These reports are sent using the FTP site. STDLRRB laboratory should notify the sentinel sites POC via email that reports are available in the FTP folder.

### **3.3.2. Description of DSTDP SDSB activities**

1. Perform site visits, as needed, to sentinel sites.

2. Implement data collection protocols, including modification of data collection forms when necessary and complying with Office of Management and Budget requirements.
3. Perform data management.
4. Review data monthly and communicate to each sentinel site if there are data inconsistencies or significant data missingness.
5. Review and analyze clinical, demographic, and antimicrobial susceptibility data; communicate important clinical findings to STD programs and others.
6. Provide regional and site-specific data in electronic format to sites participating in GISP only and/ or GISP/eGISP (Part A or Part B) on a per request basis.
7. Prepare and distribute an annual report summarizing project findings.
8. Request GISP and eGISP (Part A) isolates from ARLN laboratories for archival storage in CDC Biorepository.
9. Address human subject research issues for the project.
10. Update the protocol, coding guide, data collection forms, and website, as needed.
11. Review and analyze data from remnant NAAT samples of *N. gonorrhoeae* positive samples
12. Review and analyze clinical, demographic, and laboratory data from *N. meningitidis* isolates
13. Assist with data management and annual reports regarding data related to *N. meningitidis* isolates

### **3.3.3. Description of DSTDP STDLRRB Activities**

1. Perform site visits to GC ARLN laboratories as needed.
2. Train GC ARLN laboratory personnel when necessary.
3. Provide technical, laboratory assistance to GC ARLN and GISP/eGISP (Part A and Part B) sentinel sites.
4. Accession isolates that are sent to CDC into the ELIMS database.
5. Select, evaluate, and distribute to regional laboratories (1) Difco GC medium base for antimicrobial susceptibility testing, (2) antimicrobial powders that do not require Material Transfer Agreements (e.g., penicillin, etc.), and (3) control strains.
6. Confirm antimicrobial susceptibility results for alert isolates, and other isolates as needed within 4 weeks of receipt of isolates in STDLRRB.
7. Distribute External Quality Assessment (EQA) cultures twice annually to GC ARLN labs; prepare and distribute biennial EQA reports.
8. Perform molecular epidemiologic characterization and analysis of selected isolates (e.g. isolates with cefixime MICs  $\geq 0.25$   $\mu\text{g}/\text{ml}$ , ceftriaxone MICs  $\geq 0.125$   $\mu\text{g}/\text{ml}$ , or azithromycin MICs  $\geq 2.0$   $\mu\text{g}/\text{ml}$ , and other isolates of interest). Molecular characterization of isolates collected under this protocol may include genome sequencing and other advanced molecular detection approaches.
9. Perform identification and analysis of novel antimicrobial susceptibility patterns among isolates that require further investigation.
10. Assist with analysis of antimicrobial susceptibility data.
11. Conduct Etest® (bioMérieux, Durham, NC) and agar dilution confirmatory testing for endpoints of any isolates that have phenotypic antimicrobial susceptibility greater than the highest dilution tested by the ARLN.
12. Conduct molecular testing for known resistance-associated genetic mutations on remnant NAAT samples submitted by participating eGISP (Part B) sentinel sites
13. Return aggregate molecular testing results to participating sentinel sites quarterly
14. Coordinate annual meeting with GC AR Lab Network members at CDC, in collaboration with the Association of Public Health Laboratories (APHL).
15. Provide WGS protocols and technical support to GC AR Lab Network lab staff.
16. Monitor isolate flow, sequence selection and sequencing capacity throughout the GC AR Lab Network in order to ensure timely sequencing.
17. Ensure data is accurately transferred between GC AR Lab Network and CDC DSTDP.
18. Retrieve WGS data from GC AR Lab Network labs. Provide analysis of WGS (QC, assemblies, sequence

- typing, antimicrobial resistance (AMR) profile analysis, phylogenetic comparisons).
17. Provide guidance for sentinel sites and GC ARLN laboratories regarding handling, storing, and shipping *N. meningitidis* isolates as needed.
  18. Store all *N. meningitidis* specimens for future evaluation and analysis

## 4. General Project Issues

### 4.1. Quality Assurance

It is expected that sentinel sites, ARLN laboratories, and CDC perform the tasks described in this protocol in a timely and efficient manner within the prescribed deadlines. A summary of the GISP and eGISP (Part A and Part B) timelines for project participants are found in Table 2. *Summary of Responsibilities and Timelines for Project Participants*. Any sentinel site facing difficulties in adhering to this protocol, including difficulties with isolate collection, with remnant NAAT sample submission, and with clinical/demographic data collection, should be referred to the GISP Project Officer at CDC. Any sentinel site facing difficulties in working with their assigned ARLN should be referred to the CDC ARLN coordinator at ARLN@cdc.gov.

The duties listed in this protocol for the various GISP and eGISP (Part A and Part B) participating sites may overlap in many areas. Frequent communications among individuals at participating GISP and eGISP sites are to be conducted to monitor the day-to-day activities of the project. Conference calls and meetings between sentinel sites and CDC and between sentinel sites and their assigned ARLN laboratory may be scheduled as needed.

### 4.2. Human Subjects

The GISP/eGISP protocol is reviewed by the Office of the Associate Director for Science (ADS), NCHHSTP, CDC periodically. Most recently, this was done in February 2021 and both GISP and eGISP (Part A and Part B) were determined to be surveillance and disease control activities, and not human subjects research.

### 4.3. Office of Management & Budget

The GISP/eGISP protocol has been reviewed and approved by the Office of Management and Budget (OMB Control Number 0920-0307, expiration 08/31/2021).

### 4.4. Publication of GISP/eGISP Data

In order to make GISP and eGISP (Part A and Part B) data widely available, CDC publishes GISP and eGISP data in annual project profiles and in other CDC reports, conference abstracts, and peer-reviewed manuscripts. Manuscripts describing analyses of data from an individual sentinel site or an outbreak investigation at a specific sentinel site should involve staff from the relevant sentinel site.

Local use of GISP/eGISP (Part A and Part B) data is encouraged. Sentinel sites can develop conference abstracts and manuscripts for peer-reviewed publication based on local GISP and eGISP (Part A and Part B) data, including analyses which combine GISP/eGISP data with other data sources or for which the described analyses expand substantially beyond GISP/eGISP susceptibility data. In such cases, sentinel sites should acknowledge GISP/eGISP as the source of data in the Methods Section, and if appropriate, sentinel sites are encouraged to collaborate with the ARLN laboratory that conducted the susceptibility data. CDC co-authorship is decided on a case-by-case basis. Sentinel sites are asked to provide the GISP/eGISP Principal Investigators at CDC with courtesy copies of submitted abstracts and manuscripts.

## **4.5. Use of GISP/eGISP Isolates and Data**

GISP/eGISP isolates are collected primarily for surveillance of *N. gonorrhoeae* susceptibility, but some uses of GISP/eGISP isolates and GISP/eGISP data that are not described in this protocol may be desirable and may enhance the public health usefulness of this project.

To ensure adequate communication and address any human subjects issues that may arise with the use of isolates or data collected for public health surveillance, proposals by external parties for use of GISP/eGISP isolates or GISP/eGISP data not described in this protocol should be initiated through the following process:

1. A brief (i.e., 1–2 page) written proposal should be provided to the GISP/eGISP Principal Investigators for CDC review.
2. If appropriate, consent and/or collaboration of the relevant sentinel site state or local STD programs that provided the isolates should be sought (and appropriateness can be determined by the CDC GISP/eGISP team based on the nature of the project).
3. Institutional Review Board (IRB) review should be sought as appropriate.

Submission of the proposal to the DSTDP GISP/eGISP Principal Investigators at CDC is requested as a first step to ensure that projects do not overlap with work already in progress and to allow an assessment of whether the proposed project fits within the non-human subject research determination at CDC or requires IRB review.

An exception to this process is when isolates are already collected dually under GISP/eGISP and another ongoing protocol. In that case, appropriate consents and/or collaborations of the persons collecting and processing the isolates should already have been obtained. Local IRB review should be sought as appropriate.

Sentinel sites and regional laboratories are asked to notify the CDC GISP/eGISP Principal Investigators of proposed local uses of isolates collected through GISP/eGISP. CDC-led manuscripts involving the isolates collected through GISP/eGISP are a collaborative effort across divisions and authorship is determined based individual contribution, the pathogen, and research question. For collaborative projects, *N. meningitidis* isolates stored in the CDC Bacterial Meningitis Laboratory and the CDC STD Laboratory Reference & Research Branch (STDLRRB), *N. gonorrhoeae* isolates stored in CDC Biorepository, and data can be made available upon request via a proposal and data use agreement.

## 5. Clinical/Demographic Data Elements

### 5.1 Core GISP Data Elements

Variable Name	Type/Length	Description	Values	Comments
CLINIC	[Char, 3]	Sentinel site code	ALB = Albuquerque ANC= Anchorage BAL= Baltimore BHM=Birmingham CHI=Chicago CLE=Cleveland COL=Columbus DAL=Dallas DEN=Denver GRB=Greensboro HON=Honolulu IND=Indianapolis KCY=Kansas City LVG=Las Vegas LA1/LA2=Los Angeles MIL=Milwaukee MIN=Minneapolis NOR>New Orleans NYC= New York City ORA=Orange County PHI=Philadelphia PHX=Phoenix PIT=Pittsburgh PON=Pontiac POR=Portland SDG=San Diego SEA= Seattle SFO=San Francisco TRP=Tripler WDC= Washington, DC	
CLINID	[Char, 1]	Clinic identifier	1, 2, 3...9	For Sentinel Sites using more than one clinic to

Variable Name	Type/Length	Description	Values	Comments
		number		collect the eGISP samples, the clinic code should be entered here. Each clinic is assigned a single-digit code by the Sentinel Site; codes and the corresponding clinic names should be given to the eGISP data manager. Any changes in participating clinics should be communicated to the eGISP data manager.
<b>GISP_SPEC_ID</b>	[Char, 13]	GISP ID	e.g., NYC-202103-07	To maintain consistency for sentinel sites who are also funded for GISP activities, isolates from the first 25 male patients with gonococcal urethritis will be considered “GISP isolates”; therefore, eGISP sites that are also GISP sites should assign and maintain a GISP ID locally constructed by concatenating the variables of sentinel site code+year month+GISP isolate ID number, separated by hyphens.
<b>PATIENT_GENDER</b>	[Char, 1]	Patient Gender	1=male 2=female 3=trans male 4=trans female 5=non-binary/trans other 9=unknown	
<b>ETHNIC</b>	[Char, 1]	Hispanic	1=Hispanic or Latino 2=not Hispanic or Latino 9=unknown	This question pertains to patients of Hispanic origin and/or native Spanish speakers. If this information is solicited for the patient's record, please code accordingly. Do not assume a patient's ethnicity based on surname alone, as people can change their names, be adopted, etc. Use only self-reported ethnic status. Furthermore, <i>note that race and ethnicity are not mutually exclusive variables</i> . Individuals who indicate their ethnicity as "Hispanic" are not necessarily "white." If the information is unavailable, please code this item "9" to indicate "unknown." If the patient is described as "Hispanic" with no

Variable Name	Type/Length	Description	Values	Comments
				accompanying race data, please code "1" for ethnicity.
<b>AMIND</b>	[Char, 1]	American Indian/ Alaskan Native	1=yes, 2=no, 9=unknown	It is important to be as precise as possible with regard to demographic data as it may be used as an indicator of, or proxy for, other variables affecting morbidity outcomes such as socioeconomic status. We realize that data on race may not be collected at each site; however, where the information is available, please use the following guidelines in coding these data. <b>Self-reported race status is considered to be the most valid.</b> If race is not self-reported in the clinic record, but is noted by the clinician, this information may be used. If there is a conflict between the two, e.g., the patient self-reports that racial status is "white," but the clinician describes patient as "black," use the self-reported status. You should respond "yes" for all race categories that apply.
<b>ASIAN</b>	[Char, 1]	Asian	1=yes, 2=no, 9=unknown	
<b>BLACK</b>	[Char, 1]	Black	1=yes, 2=no, 9=unknown	
<b>NAHAW</b>	[Char, 1]	Native Hawaiian/ Pacific Islander	1=yes, 2=no, 9=unknown	
<b>WHITE</b>	[Char, 1]	White	1=yes, 2=no, 9=unknown	
<b>ORACE</b>	[Char, 1]	Other race	1=yes, 2=no, 9=unknown	
<b>DATEVIS</b>	[Date]	Date of clinic visit	MM/DD/YYYY	Enter the month, day, and year of the clinic visit at which the positive gonorrhea culture was obtained. If the day is unknown, enter "01" for day. The year and month should correspond to the year and month entered for item 2 above.
<b>AGE</b>	[Num, 2]	Age in years	1, 2, 3...98 99=unknown	
<b>CISFEM</b>	[Char, 1]	Cis female partners	1=yes, 2=no, 9=unknown	Gender of the patient's sexual partners within the past 3 months. You should respond "yes" for all gender categories that apply.
<b>CISMAL</b>	[Char, 1]	Cis male partners	1=yes, 2=no, 9=unknown	
<b>TRANSFEM</b>	[Char, 1]	Trans female partners	1=yes, 2=no, 9=unknown	
<b>TRANSMAL</b>	[Char, 1]	Trans male partners	1=yes, 2=no, 9=unknown	In clinics where gender of sex partner is not directly ascertained from the patient, you should respond "yes" for "female partners (unknown gender)" and/or "male partners (unknown gender)" categories that apply. In clinics where

Variable Name	Type/Length	Description	Values	Comments
<b>UNKFEM</b>	[Char, 1]	Female partners (unknown gender)	1=yes, 2=no, 9=unknown	sex or gender of sex partner is not directly ascertained from the patient, code "9" for "unknown" in the cis and trans partner categories.
<b>UNKMALE</b>	[Char, 1]	Male partners (unknown gender)	1=yes, 2=no, 9=unknown	
<b>SYMP</b>	[Char, 1]	Presence of gonorrhea symptom(s) at anatomic site of isolate	1=symptoms present 2=no symptoms present 9=unknown	<p>This question pertains to the presence of symptoms of gonorrhea at the genital and/or extra-genital site where the isolate was collected. Symptoms of gonorrhea include the following:</p> <ul style="list-style-type: none"> <li>- Urethral infection: urethral discharge and/or dysuria (pain with urination)</li> <li>- Endocervical infection: vaginal discharge and/or dysuria</li> <li>- Rectal infection: rectal discharge, rectal pain, and/or tenesmus (pain with passing bowel movements)</li> <li>- Pharyngeal infection: sore throat</li> </ul> <p>If there are no data in the record regarding the presence OR absence of gonorrhea symptoms as described above, code this field "9" indicating "unknown symptomatology."</p>
<b>HISTORY</b>	[Char, 1]	Previous history of gonorrhea (ever)	1=yes 2=no 9=unknown	Please note any previous documented or self-reported history of gonorrhea in patient's lifetime. If there is no information concerning history in the record, code "9" to indicate "unknown."
<b>EPSDS</b>	[Num, 2]	Number of previous episodes within the past 12 months	0=no documented episodes 99=unknown	Enter the number of previous episodes of gonorrhea documented in the patient's record within the past 12 months.
<b>HIVSTAT</b>	[Char, 1]	HIV status at time of clinic visit for	1=positive 2=negative	Enter patient's HIV status as known at the time of the clinic visit for gonorrhea. Code "1" for

Variable Name	Type/Length	Description	Values	Comments
		gonorrhea	3=indeterminate 9=unknown	"positive" if the patient's medical record documents a positive HIV test or if the patient self-reports as HIV-positive. This can include rapid tests for which results are available on the day of the clinic visit. Code "2" for "negative" if the patient's medical record documents a negative HIV test within the previous 3 months. If the available information does not allow you to code "1" or "2," then code "9" for "unknown."
<b>TRAVEL</b>	[Char, 1]	Travel outside of US in past 60 days	1=yes 2=no 9=unknown	Code "1" for "yes" if the patient traveled outside of the United States (50 U.S. states) during the previous 60 days. Code "2" for "no" if the patient did not travel internationally during the previous 60 days. If travel information is not available, code "9" for "unknown."
<b>SEXWK</b>	[Char, 1]	History of giving or receiving drugs/money in the past 12 months	1=yes 2=no 9=unknown	If the patient exchanged drugs or money for sex (or exchanged sex for drugs or money) during the previous 12 months, code "1" for "yes." If the patient did not exchange drugs or money for sex (or sex for drugs or money), code "2" for "no." If it is unknown whether the patient had sex work exposure, code "9" for "unknown." Do not code "2" for "no" by default.
<b>ANTIBIOT</b>	[Char, 1]	Antibiotic use in the past 60 days	1=yes 2=no 9=unknown	Code "1" for "yes" if the patient took antibiotics for any reason during the previous 60 days. This should only include systemic oral or injectable antibiotics, and should not include antibiotic ointments or eye drops. Code "2" for "no" if the patient did not take antibiotics for any reason during the previous 60 days. If it is unknown whether or not the patient took antibiotics, code "9" for "unknown." Do not code "2" for "no" by default.

Variable Name	Type/Length	Description	Values	Comments
IDU	[Char, 1]	History of injection drug use in the past 12 months	1=yes 2=no 9=unknown	Code "1" for "yes" if the patient reported using recreational injection drugs during the previous 12 months. Code "2" for "no" if the patient reported not doing recreational injection drugs during the previous 12 months. If it is unknown whether or not the patient used recreational injection drugs, code "9" for "unknown." Do not code "2" for "no" by default.
NONIDU	[Char, 1]	History of non-injection drug use in the past 12 months	1=yes 2=no 9=unknown	Code "1" for yes if the patient reported using recreational non-injection drugs during the previous 12 months. Examples: ecstasy, crack, cocaine, marijuana, methamphetamines, poppers (but excluding alcohol, medications for erectile dysfunction, and steroids). Code "2" for "no" if the patient reported not doing recreational non-injection drugs during the previous 12 months. If it is unknown whether or not the patient used recreational non-injection drugs, code "9" for "unknown." Do not code "2" for "no" by default.
TRMT1	[Char, 2]	Primary treatment for gonorrhea	00=none 03=spectinomycin (Trobicin) 2 gm 04=ceftriaxone (Rocephin) 250 mg 05=ceftriaxone (Rocephin) 125 mg 06=ciprofloxacin (Cipro) 500 mg 07=cefoxitin (Mefoxin) 2 gm 12=cefixime (Suprax) 400 mg 14=cefpodoxime proxetil (Vantin) 200 mg 15=ofloxacin (Floxin) 400 mg 17=ceftizoxime (Cefizox) 500 mg 18=cefotaxime (Claforan) 500 mg 21=azithromycin (Zithromax) 2 gm 22=levofloxacin (Levaquin) 250 mg 23=cefpodoxime proxetil (Vantin) 400 mg	Indicate the primary antimicrobial prescribed to treat the case of gonorrhea. If entering the code "88" for "other," include the name of the drug in the space provided. If no treatment for gonorrhea was given, code "00." You must enter both digits of the treatment code, including leading zeros. Please note that "01" and "02" are not valid codes.  NOTE: The following gonorrhea treatments were added January 2021. 29: Ceftriaxone 500 mg 30: Ceftriaxone 1g 31: Cefixime 800 mg

Variable Name	Type/Length	Description	Values	Comments
			24=ceftibuten (Cedax) 400 mg 25=cefdinir (Omnicef ) 300 mg 26=cefdinir (Omnicef ) 600 mg 27= gemifloxacin 320 mg 28= gentamicin 240 mg (or weight-based dosage) 29=Ceftriaxone 500 mg 30=Ceftriaxone 1g 31=Cefixime 800 mg 88=other (please indicate in Other Treatment 1) 99=unknown	
<b>OTHTRMT1</b>	[Char, 15]	Other treatment not listed as code for TRMT1	If code "88" was entered for Treatment 1, please type in the name and dosage of the drug used for primary treatment of gonorrhea.	If code "88" ("other") was entered for Treatment 1, write in the name and dosage of the primary antimicrobial therapy for gonorrhea and dosage that was administered.
<b>TRMT2</b>	[Char, 2]	Second antibiotic used as part of dual therapy for gonorrhea (and treatment of chlamydia)	00=none 01=ampicillin/amoxicillin 09=doxycycline (Vibramycin)/ tetracycline 10=erythromycin 11=azithromycin (Zithromax) 1 gm 15=ofloxacin 21=azithromycin (Zithromax) 2 gm 22=levofloxacin 88=other 99=unknown	From 2010 to 2020, two antibiotics were recommended for patients diagnosed with gonorrhea. Dual therapy (treatment with a cephalosporin antibiotic and either azithromycin or doxycycline) was first recommended for treatment of gonorrhea in 2010. In December 2020, CDC changed the recommended gonorrhea treatment regimen to monotherapy with ceftriaxone. Currently, some alternative treatment options include a two-drug regimen. If dual therapy was administered, indicate the second antimicrobial used. Code "88" for other only if the dual therapy did not include any of the listed treatment options. You must enter a two-digit code in this field, including leading zeros.

## 5.2 Enhanced GISP (Part A) Data Elements

Variable Name	Type/Length	Description	Values	Comments
PATIENT_ID	[Char, 18]	Patient ID	#####	An eGISP patient identifier should be created which is unique within the jurisdiction, remain consistent across visits and the life cycle of eGISP, and not contain personally identifiable information (PII).
eGISP_SPEC_ID	[Char, 18]	eGISP/SURRG ID	e.g., CHICC170107918.	For all isolates collected, sites should assign and maintain an eGISP/SURRG specimen ID for all isolates, constructed using the 3 letter sentinel site code + local PHL accession number (no hyphens or spaces).
SPECIMEN_TYPE	[Char, 2]	Anatomic site of specimen collection	U=urethral V=vaginal E=endocervical R=rectal P=pharyngeal NC=not captured	
NAAT_GC	[Char, 1]	Nucleic acid amplification test (NAAT) result	1=positive 2=negative 3=indeterminate/ equivocal 9=unknown	
POSSIBLE_NM*	[Char, 1]	Isolate suspected to be <i>N. meningitidis</i>	1=isolate may be <i>N. meningitidis</i> 2=isolate has been positively identified as <i>N. gonorrhoeae</i>	A possible <i>N. meningitidis</i> isolate is considered when an isolate has (i) the growth of typical appearing <i>N. gonorrhoeae</i> colonies with typical morphologies (e.g., small, transparent) on a selective medium such as Thayer-Martin at 35o C to 36.5o C in 5% CO2, (ii) a positive oxidase test, (iii) the observation of Gram-negative, oxidase-positive diplococci in stained smears and (iv) a negative NAAT result. If additional testing is performed to confirm

				the species of the isolate, this information can also be used to make a determination.
<b>NmVacc*</b>	[Char, 1]	Prior history of meningococcal vaccination	1= MenACWY vaccine only 2= MenB vaccine only 3= Men ACWY + MenB vaccine 4= Meningococcal/meningitis vaccine, but unknown 5= No meningitis vaccine 9= Unknown	There are several vaccines for meningitis available. The MenACWY vaccines are called Menactra or Menveo. MenB vaccines are called Trumenba and Bexsero. If it is known that a patient has received no meningococcal vaccine, please mark "No meningitis vaccine". Otherwise mark "unknown".

\*for eGISP (Part A) clinical sites participating in the optional activity

## **6. Contact Information and Mailing Addresses**

### **6.1. CDC Project Personnel**

#### **6.1.1 CDC Personnel Contact Information**

Surveillance and Data Science Branch

Division of STD Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

GISP Project Officer                   **Sancta St. Cyr, MD, MPH**

Tel: (404) 718-5447

FAX: (404) 639-8610

E-mail: [oew3@cdc.gov](mailto:oew3@cdc.gov)

GISP Data Manager                   **Alesia B. Harvey**

Tel: (404) 639-8196

FAX: (404) 639-8622

E-mail: [abj1@cdc.gov](mailto:abj1@cdc.gov)

SDSB Enhanced                       **Kristen Kreisel, PhD**

Surveillance                         Tel: (404) 718-5148

Team Lead                           FAX: (404) 639-8622

E-mail: [ltq1@cdc.gov](mailto:ltq1@cdc.gov)

SDSB Branch Chief                   **Hillard S. Weinstock, MD, MPH**

Tel: (404) 639-2059

FAX: (404) 639-8622

E-mail: [hsw2@cdc.gov](mailto:hsw2@cdc.gov)

GISP FTP Manager                   **Marvin Fleming**

Tel: (404) 639-8352

FAX: (404) 639-8622

E-mail: [mqf6@cdc.gov](mailto:mqf6@cdc.gov)

STD Laboratory Reference and Research Branch

Division of STD Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Prinicipal Investigator

**Cau Pham, PhD**

Tel: (404) 718-5642

FAX: (404) 639-2130

Email: [whi4@cdc.gov](mailto:whi4@cdc.gov)

STDLRRB Gonorrhea

**Brian H. Raphael, PhD**

Team Lead

Tel: (404) 639-4292

FAX: (404) 639-2130

Email: [elx9@cdc.gov](mailto:elx9@cdc.gov)

STDLRRB Branch Chief

**Ellen Kersh, PhD**

Tel: (404) 639-2728

FAX: (404) 639-3976

E-mail: [egk6@cdc.gov](mailto:egk6@cdc.gov)

Microbiologist

**Evelyn Nash, PhD**

Tel: (404) 718-5037

FAX: (404) 639-2130

E-mail: [lmq5@cdc.gov](mailto:lmq5@cdc.gov)

Biologist

**Samera Sharpe**

Tel: (404) 639-2875

FAX: (404) 639-2130

E-mail: [bpu7@cdc.gov](mailto:bpu7@cdc.gov)

Laboratory Quality Manager

**Carol Bolden**

Tel: (404) 639-5466

FAX: (404) 639-2130

E-mail: [lhw8@cdc.gov](mailto:lhw8@cdc.gov)

### **6.1.2 CDC STAT Laboratory Contact and Shipping Addresses**

The contact information and shipping addresses for the CDC/STAT lab are as follows:

For *Neisseria gonorrhoeae* isolates:

Marla Petway  
Centers for Disease Control and Prevention RDSB/STAT  
ATTN: Unit 31 CARB Study  
1600 Clifton Road, NE  
Atlanta, GA 30333  
Office: 404-718-5642

Email: [whi4@cdc.gov](mailto:whi4@cdc.gov) (Cau Pham, PhD)

For *Neisseria gonorrhoeae* remnant NAAT samples:

Marla Petway  
Centers for Disease Control and Prevention RDSB/STAT  
ATTN: Unit 31 CARB Study  
1600 Clifton Road, NE  
Atlanta, GA 30333  
Office: 404-718-5037

Email: [lmq5@cdc.gov](mailto:lmq5@cdc.gov) (Evelyn Nash, PhD)

For *Neisseria meningitidis* isolates:

c/o M Marla Petway

Centers for Disease Control and Prevention RDSB/STAT  
ATTN: Unit 31 CARB Study  
1600 Clifton Road, NE  
Atlanta, GA 30333  
Office: 404-718-5642

Email: [whi4@cdc.gov](mailto:whi4@cdc.gov) (Cau Pham, PhD)

## **6.2 ARLN Project Laboratory Personnel**

The contact information and shipping address for the ARLNs are as follows:

### **Maryland Department of Health and Mental Hygiene**

Key Contact:

David Torpey, Sc.D., M(ASCP)

Manager, Public Health Microbiology Laboratories

Maryland Department of Health and Mental Hygiene

1770 Ashland Ave., Microbiology Laboratories

Baltimore, MD 21205

Phone: 443-681-3951

[david.torpey@maryland.gov](mailto:david.torpey@maryland.gov)

Shipping Address:

Maryland Dept. of Health and Mental Hygiene

Laboratories Administration

1770 Ashland Ave.

Baltimore, MD 21205

### **Tennessee Department of Health**

Key Contact:

Zachary Perry | GC Project Supervisor

General Bacteriology & Environmental Microbiology

Division of Laboratory Services

4th Floor South

630 Hart Lane, Nashville, TN 37243

Phone: 615-741-3437

Fax: 615-262-6393

Zachary.Perry@tn.gov

Shipping Address:

General Bacteriology & Environmental Microbiology

Division of Laboratory Services

4th Floor South

630 Hart Lane, Nashville, TN 37243

### **Utah Department of Health**

Key Contact:

Lori Smith | GC Project Supervisor

Utah Public Health Laboratory

4431 South 2700 West

Taylorsville, UT 84129

Phone: 801-965-2503

lhsmith@utah.gov

Shipping Address:

Utah Public Health Laboratory

4431 South 2700 West

Taylorsville, UT 84129

### **Washington State Department of Health**

University of Washington

Key Contact:

Olusegun O. Soge, PhD

Laboratory Director, UW Neisseria Reference Laboratory & Chlamydia Laboratory  
Harborview Medical Center  
Global Health/CFAS  
325 9th Ave, Box 359931  
Seattle, WA 98104  
Phone: 206-897-5325  
Fax: (206) 897-5304  
[sogeo@u.washington.edu](mailto:sogeo@u.washington.edu)

Washington State Department of Health, Public Health Laboratories

Key Contact:

Michael Tran | GC Project Supervisor

Washington State Department of Health

Public Health Laboratories

Division of Disease Control and Health Statistics

1610 NE 150th Street

Shoreline, WA 98155

Phone: 206-418-5459

[Michael.Tran@doh.wa.gov](mailto:Michael.Tran@doh.wa.gov)

FedEx, UPS and Express courier mailing address:

Neisseria Reference Laboratory

Harborview Medical Center

3NJ342A

908 Jefferson St.

Seattle, WA 98104

Phone: (206) 897-5324

## Appendix A: Naming Conventions

Type of Report	Naming Convention	Example
<b>Documents Coming From Sentinel Sites</b>		
<b>Shipping Manifest – <i>N. gonorrhoeae</i></b>	3-digit sentinel site code_Month of Collection (as 2 digits)_Year of collection (as 4 digits)_GC Project_Routine	GISP only example: PHI_05_2021_GISP_Routine
		GISP/eGISP example: NOR_05_2021_eGISP_Routine
<b>Shipping Manifest – <i>N. meningitidis</i></b>	sentinel site code_month_year_Nm	eGISP only example: ORA_05_2021_Nm
<b>Clinical and demographic data</b>	sentinel site code_month_year_Epi	GISP only example: POR_05_2021_GISP_Epi.xls
		GISP/eGISP example: COL_05_2021_eGISP_Epi.xls
<b>Documents Coming From ARLNs</b>		
<b>Aggregate AST Report to Sentinel Sites</b>	3-digit sentinel site code_Month of testing (as 2 digits)_Year of testing (as 4 digits)	IND_03_2022
<b>Alert to Sentinel Site</b>	Add “_Alert1” (for the first alert file sent to the site that month), “_Alert2” (for the second alert file sent to the site that month), “_Alert3” etc... to the end of the above naming convention	IND_03_2022_Alert1
<b>Aggregate AST Repot to CDC</b>	GC AR Lab Network State_Month of testing (as 2 digits)_Year of testing (as 4 digits)	MD_03_2022
<b>Alert or Quick-Send to CDC</b>	Add “_Alert1” (for the first alert file sent to the site that month), “_Alert2” (for the second alert file sent to the site that month), “_Alert3” etc... to the end of the above naming convention	WA_03_2022_Alert1
		WA_03_2022_Alert2
		WA_Quick-Send_01
	SURGG sentinel sites only: Replace ‘Routine’ with ‘Alert_Shipment Number’ or ‘Quick-Send_Shipment Number’ on the shipping manifest name	SFO_05_2022_SURRG_Alert_01
<b>Quarterly shipment of Alert isolates</b>	AR Lab Network State_Year_Qarter_Alert	TN_2021_Q2_Alert
<b>Quarterly shipment of WGS isolates</b>	AR Lab Network State_Year_Qarter_WGS	TN_2021_Q1_WGS
<b>Semi-annual shipment of ‘susceptible’ isolates</b>	AR Lab Network State_Archive	TN_Archive

# Appendix B: Instructions for Use of CDC Private File Transfer Portal (FTP)

## How to connect to FTPs

Shipping Manifests (SM) are saved in FTP sites. To access and download SM, you will need to log into the FTP site by using client software, such as FileZilla and WinSCP, or the computer's File Explorer. This section provides instructions for logging into the FTPs using each of these methods.

**Note:** Filezilla and WinSCP can be used to access **both** private and encrypted FTPs. The computer's File Explorer can be used to access **only** private FTPs.

Private FTP:

GCWest (WA PHL)

GCMountainU (UT PHL)

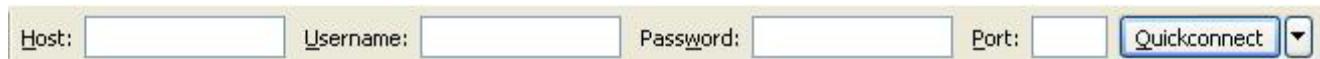
Encrypted FTP:

GCSoutheast (TN PHL)

GCMidAtlantic (MD PHL)

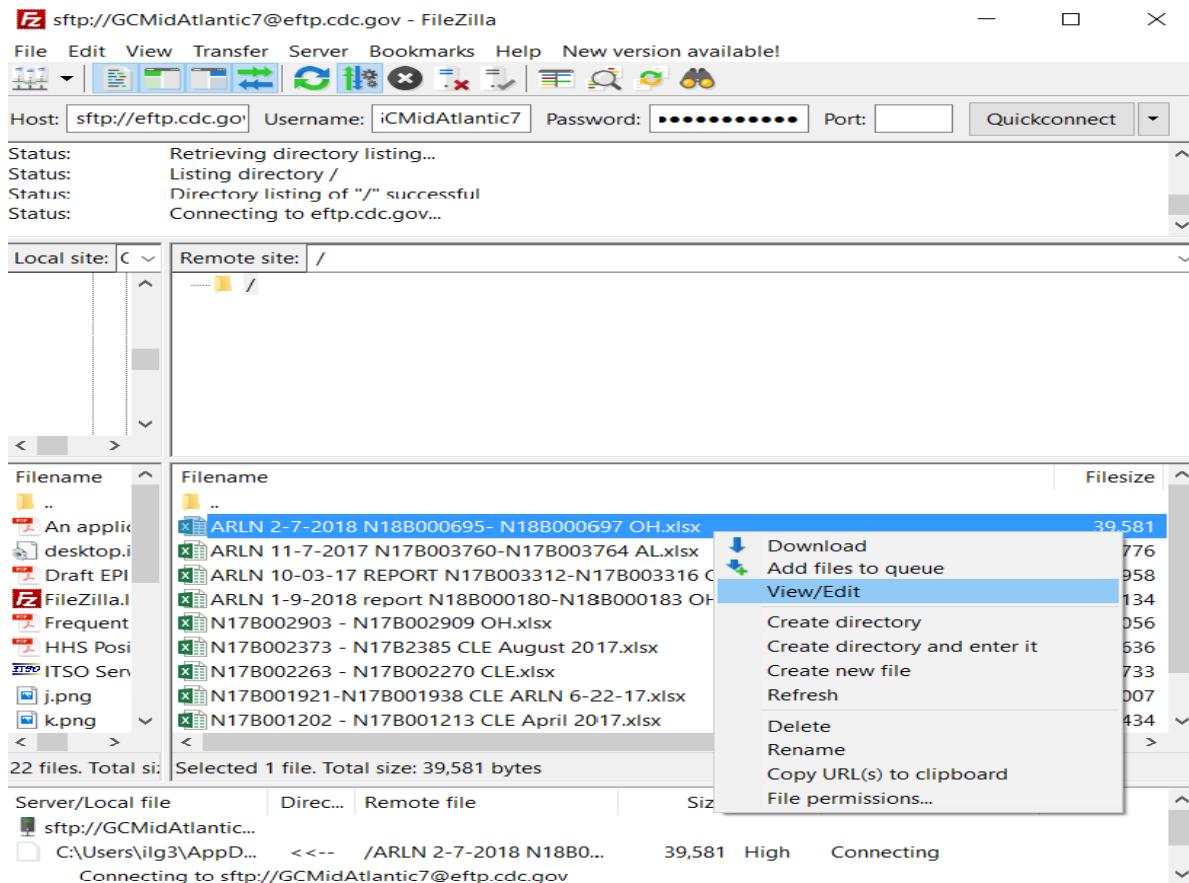
A. Using Filezilla:

1. Open FileZilla



- i. Enter the address of the server in the field **Host**, located in the **Quickconnect** bar.  
**host:**
  - For encrypted FTP use: **sftp://eftp.cdc.gov**
  - For private FTP use: **<ftp://sftp.cdc.gov>**
- ii. Enter user name  
FTP account: **xxx**
- iii. Enter password  
Password: **xxxx**
- iv. Enter the port number (port **21** for Private FTP and **22** for Encrypted [S]FTP)
- v. Click on **Quickconnect** or press **Enter** to connect to the server.
- vi. Click **OK** when you get a warning about an unknown host key. (The first time you connect to the FTP server you may be asked to verify that it is a trusted site. Check the "Always trust certificate in future sessions" box. Then click "OK" to continue)

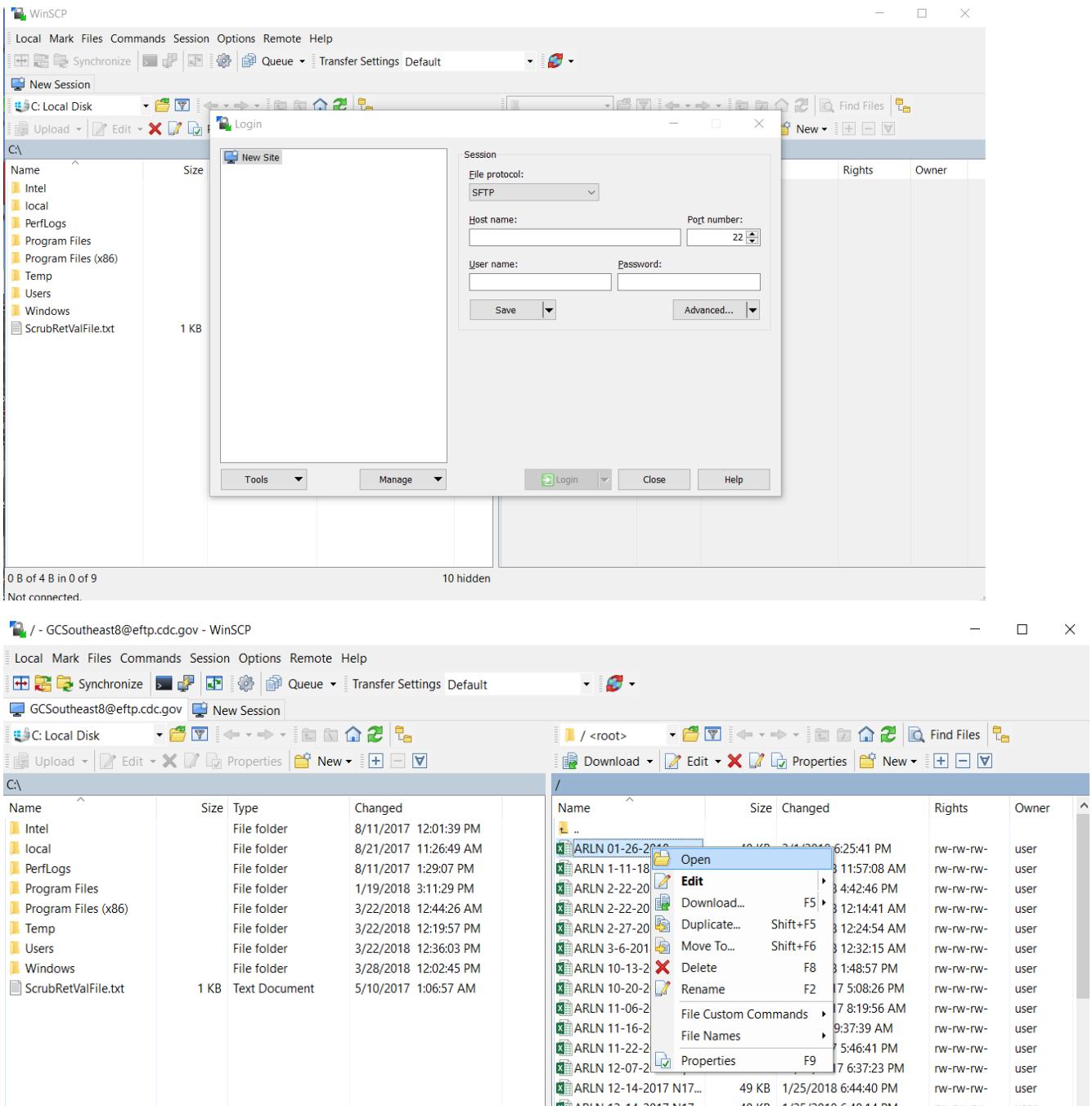
2. To download and save a file to your computer, **right click** on the desired file and select “View/Edit”. Once the file opens, you will be able to save it to your computer.



#### B. Using WinSCP:

1. Open WinSCP
  - i. Enter the address of the server in the field **Host name**  
**host name:**
    - For encrypted FTP use: <sftp://eftp.cdc.gov>
    - For private FTP use: <ftp://sftp.cdc.gov>
  - ii. Enter user name  
FTP account: **xxx**
  - iii. Enter password  
Password: **xxxx**
  - iv. Enter the port number (port **21** for Private FTP and **22** for Encrypted [S]FTP)

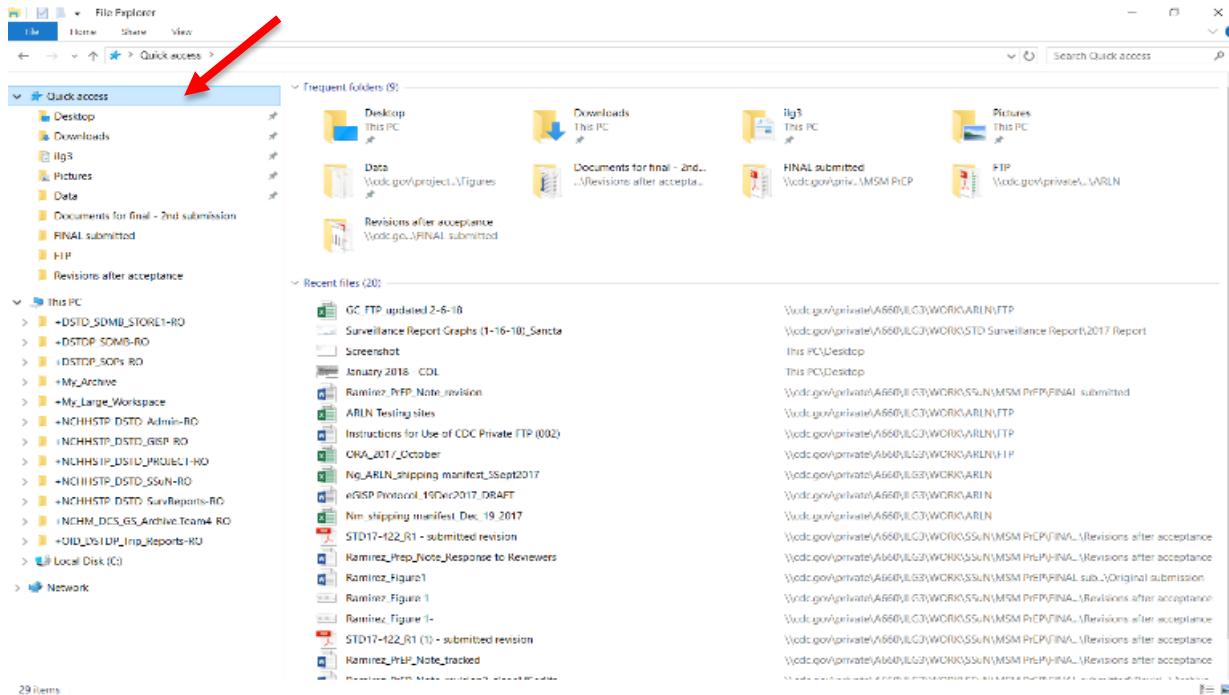
v. Click on **Login** or press **Enter** to connect to the server.



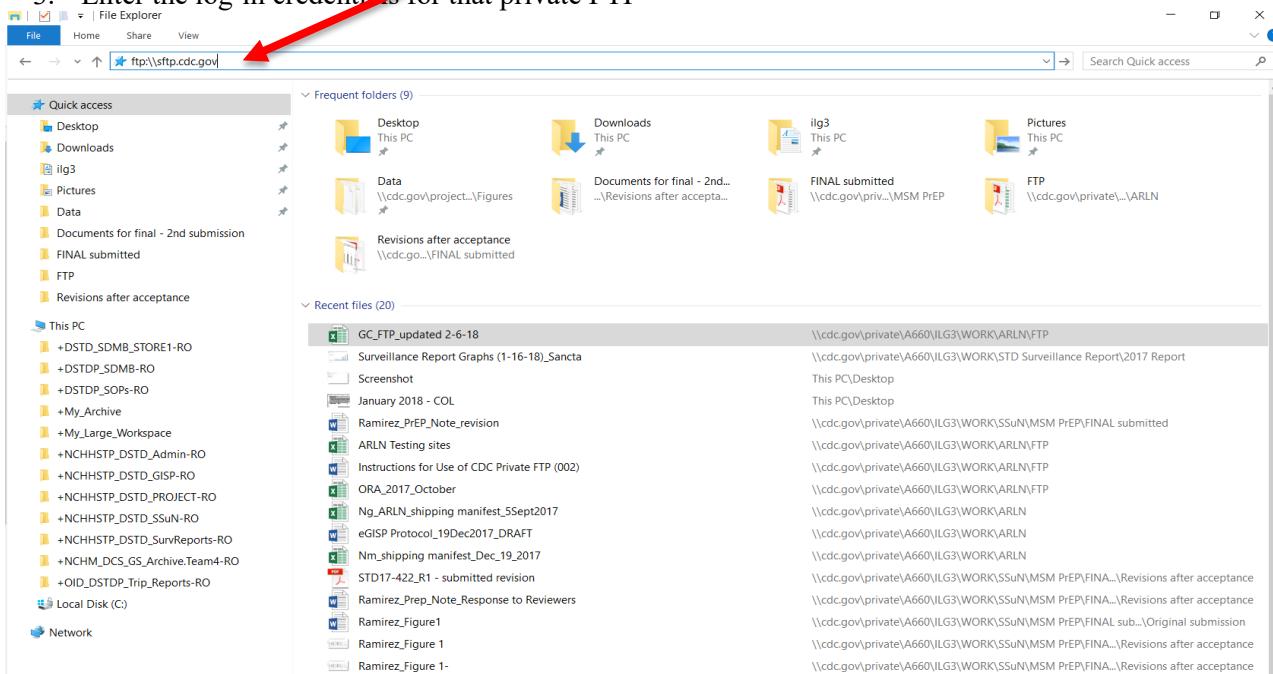
2. To download and save a file to your computer, right click on the desired file and select “Open”. Once the file opens, you will be able to save it to your computer. You can also select “Download” to directly save it to your computer.

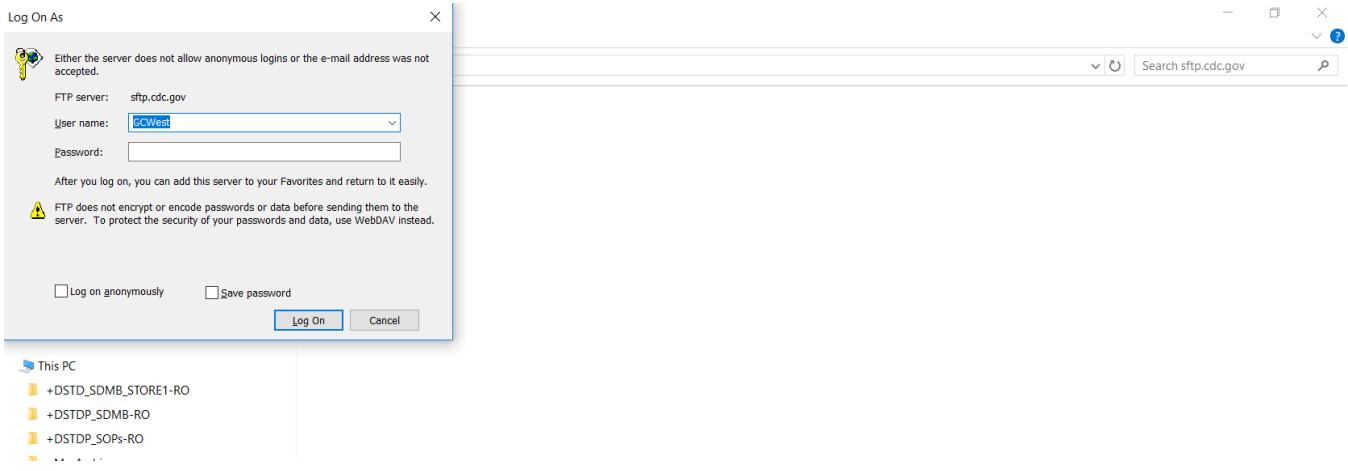
C. Using the computer’s File Explorer – Use **ONLY** for **PRIVATE** FTPs:  
NOTE: Only works in computers with **Windows 10** or later versions.

1. First, go to the File Explorer. Click on “**Quick access**”.

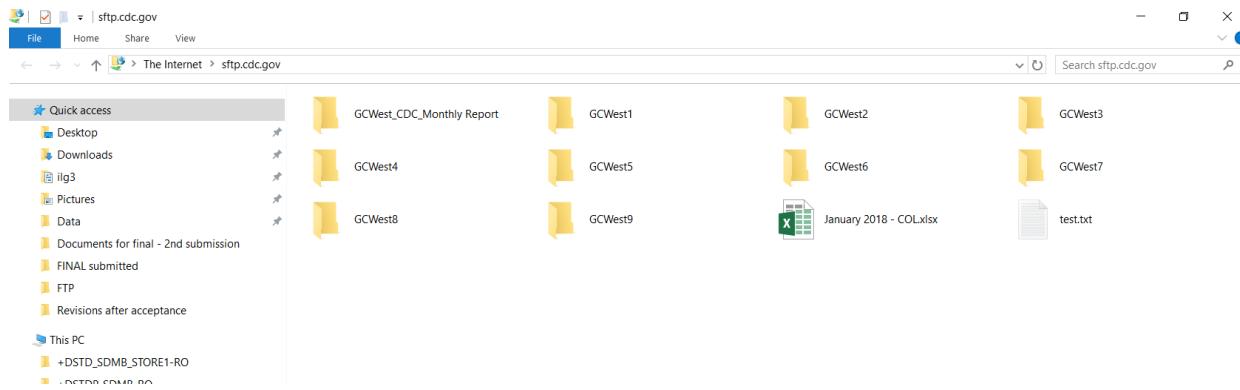


2. Type “**ftp:\\sftp.cdc.gov**” on the bar (click “Enter”):
3. Enter the log-in credentials for that private FTP





4. You're in! Now you can see all the folders within the private FTP site.



## Contacts

For technical assistance on any FTP issue, contact Marvin Fleming ([mqf6@cdc.gov](mailto:mqf6@cdc.gov)), FTP site Manager.

For questions/issues related to GISP sites, contact Sancta St. Cyr ([oew3@cdc.gov](mailto:oew3@cdc.gov)), GISP/eGISP Project Officer.

For questions/issues related to SURRG sites, contact Karen Schlanger ([khs4@cdc.gov](mailto:khs4@cdc.gov)), SURRG Project Officer.

For questions/issues related to GISP/eGISP data, contact Alesia Harvey ([abj1@cdc.gov](mailto:abj1@cdc.gov)), Data Manager.