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

Protocol

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1. Introduction

1.1. Background

Gonorrhea is the second most commonly reported notifiable disease in the United States with over 580,000 cases reported in 2018. The treatment and control of *Neisseria gonorrhoeae* infections 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 United Sates. 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, and 2015.

In 2013, the Centers for Disease Control and Prevention (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. 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 (DSTDP) supports activities that aim to slow the development of antibiotic-resistant gonorrhea and prevent its spread. To build robust capacity for culture-based antimicrobial susceptibility testing 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), the expanded project, 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. Urethritis associated with *N. meningitidis* has recently been identified with increasing frequency in at least two GISP sites. Given that *N. meningitidis* urethritis/cervicitis is not a reportable disease in the United States, 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.

GISP continues to be the core gonococcal surveillance system in the United States. By expanding GISP, eGISP may improve the ability to detect changes in susceptibility patterns, detect resistant infections sooner and inform efforts to maximize specificity of surveillance. This is the combined protocol for both projects and supersedes all previous protocols for each of the individual projects.

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

2019 under the ELC Funding opportunity announcement for GISP and eGISP 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 eGISP activities, which include the collection of extragenital specimens from men and women and endocervical specimens from women. Funded eGISP sites may choose to also participate in the optional activities involving the collection of 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	Site	GISP	eGISP
Alabama	Birmingham	✓	
Alaska	Anchorage	✓	
Arizona	Phoenix	✓	✓
California	Orange County	✓	✓
	San Diego	✓	✓
	San Francisco	✓	
Chicago, IL	Chicago	✓	✓
Colorado	Denver	✓	
District of Columbia	Washington, D.C.	✓	
Florida	Miami	✓	
Hawaii	Honolulu	✓	
	Tripler Army Medical Center	✓	
Indiana	Indianapolis	✓	
Los Angeles, CA	Los Angeles	✓	
Louisiana	New Orleans	✓	✓
Maryland	Baltimore	✓	
Michigan	Pontiac	✓	✓
Minnesota	Minneapolis	✓	
Mississippi	Jackson	✓	
Missouri	Kansas City	✓	
Nevada	Las Vegas	✓	✓
New Jersey	Camden	✓	
	Paterson	✓	
New Mexico	Albuquerque	✓	
New York	Buffalo	✓	
New York City, NY	New York City	✓	
North Carolina	Greensboro	✓	
Ohio	Columbus	✓	✓
Oregon	Portland	✓	
Philadelphia, PA	Philadelphia	✓	✓
Texas	Dallas	✓	
Washington	Seattle	✓	
Wisconsin	Milwaukee	✓	

*All eGISP sites are expected to participate in core GISP activities as described in the protocol.

1.3. Objectives

GISP

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

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
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 (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 Management Branch (SDMB) and the Laboratory Reference & Research Branch (LRRB); Antibiotic Resistance Laboratory Network (ARLN) 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 data, demographic data, 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 analyses are based on clinical data, demographic data, 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**)

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

Participant	Activity	Timeline
Sentinel Sites	Clinical and Demographic Data: Collect clinical and demographic data and submit to CDC (via SAMS)	**Monthly**- 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)	**Monthly-** no later than the **first Monday** of the month following the month of collection
	Isolates: Collect and submit *N. gonorrhoeae* isolates to assigned ARLN laboratory (Include hardcopy of manifest in box)	**Monthly**- no later than the **first Monday** of the month following the month of collection
	Isolates (Optional eGISP activity): Collect and submit *N. meningitidis* isolates to CDC Laboratory Reference & Research Branch (LRRB)	Monthly
	Annual Progress Report: Complete and submit annual progress report to ELC Program CDC-RFA-CK19-1904	Annually
ARLN Laboratory	Testing of Isolates: Perform antimicrobial susceptibility testing on all submitted isolates	Within **3 weeks** of receipt of isolates
	Susceptibility Test Data: Alert results and batched results should be reported to CDC and sentinel sites	Alert results: within **24 hours** of confirmation Batched results: **monthly**
	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 *N. meningitidis* identified at the ARLN lab to CDC	Monthly
CDC	Data Files for Sentinel Sites:	**Upon request** for prior year

	Provide sentinel sites with electronic GISP and eGISP data file	data after August
	Annual Sentinel Site Reports: Publish annual GISP Profiles and eGISP Sentinel Site Reports and make them available to all sites	**Fall/ Winter** following the year of isolate collection

3.1. Sentinel Sites

3.1.1. Overview

GISP

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

In addition to GISP activities, an eGISP 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**)

Clinical/demographic data on eGISP patients are collected by eGISP sentinel sites and submitted to CDC monthly.

To participate in eGISP, 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.

At each eGISP 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/eGISP timelines are followed and that isolates are sent to the assigned ARLN laboratory or the CDC Laboratory Reference & Research Branch (LRRB) and the clinical/demographic data are sent to CDC.

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 35º C to 36.5º C in 5% CO_2, (ii) a positive oxidase test, and (iii) the observation of Gram-negative, oxidase-positive diplococci in stained smears.

eGISP

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 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 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*# isolates are collected from men and women each month. (**optional eGISP 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 35º C to 36.5º C in 5% CO_2, (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").

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

For GISP/eGISP sentinel site isolates, all cryovials should be labeled using the eGISP/SURRG specimen ID (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 Laboratory Reference & Research Branch (LRRB) confirms viability of isolate.

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 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 contracted transport carrier.

Isolates 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 and ARLN 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 Activity): Isolates of possible *N. meningitidis* should be batched to ship monthly Sentinel sites should ship possible *N. meningitidis* eGISP isolates to the Laboratory Reference & Research Branch (LRRB) at CDC on a Monday, Tuesday or Wednesday only. Avoid shipping specimens the day before or on holidays, including federal holidays. For all possible *N. meningitidis* isolate transfers, the shipping manifest for possible *N. meningitidis* isolates should be used. A hard copy of the shipping manifest should be placed in the shipping container, and the *N. meningitidis* POCs notified by email in advance to shipping of isolates. (See *3.1.2.4. Sentinel Site Laboratory Manifest Preparation and Submission*). If the NAAT for gonorrhea is negative and the isolate does not demonstrate bacterial growth consistent with *Neisseria* spp., the isolate should not be shipped to CDC.

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*). A second manifest format is used for shipping *N. meningitidis* isolates as part of eGISP (Figure 2. eGISP Manifest for *N. meningitidis*).

The manifests identify the variables that are required to be provided with the isolates shipment. Required variables vary by project; sentinel sites participating in GISP only are required to complete the sections of the manifest under the label “GISP sites only” and sentinel sites participating in both GISP and eGISP 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 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 as well as the 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 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 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 sites	Specimen source	Anatomic site of specimen; 2 characters max U = Urethral V = Vaginal E = Endocervical R = Rectal P = Pharyngeal NC = Not Captured
eGISP sites	Specimen collection date	Date of specimen collection; 10 characters (MM/DD/YYYY)
eGISP 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 sites (*optional Nm activity)*	Possible *Nm*	Yes= isolate may be *N. meningitidis* No= Isolate has been positively identified as *N. gonorrhoeae*
eGISP sites	Age	Patient age (in years; no decimals; 3 digits max)
All GISP and eGISP sites	Patient date of Birth	Patient date of birth; 10 characters (MM/DD/YYYY) Not transmitted to CDC
All GISP and eGISP sites	Facility location	Clinic where specimen was collected (see Table 4. Facility Location Codes)
All GISP and 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-201703-04

*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 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
NJ	Camden/ Paterson	CAM-01
IL	Chicago (Lakeview)	CHI-01
IL	Chicago (South Austin)	CHI-02
OH	Columbus	COL-01
TX	Dallas	DAL-01
CO	Denver	DEN-01
NC	Greensboro	GRB-01
HI	Honolulu	HON-01
IN	Indianapolis	IND-01
MS	Jackson	JAC-01
MO	Kansas City	KCY-01
NV	Las Vegas	LVG-01
CA	Los Angeles (LA LGBT West Hollywood)	LA1-01
CA	Los Angeles (LA LGBT Schrader)	LA2-01
FL	Miami	MIA-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
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. An electronic version of the manifest should be submitted to the ARLN lab through the file transfer portal (FTP) site

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

GISP/eGISP/SURRG Isolate Shipping Manifest

Instructions:
- 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							
	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
S var**	Jurisdiction_PHL	SURRG_Spec_ID	Patient_ID	Specimen_type	Specimen_collection_date	Patient_Gender	N/A	Patient_age	Patient_DOB	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											

<u>For possible *N. meningitidis* isolates (Optional: eGISP):</u> 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 *Neisseria meningitidis* Isolates

Instructions:
- 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			

	SURRG/eGISP Specimen ID	Patient ID	Specimen Source	Specimen Collection date	AGE	Gender	*Possible Nm*	Comments
Example	*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 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_2017_GISP_Routine

GISP/eGISP example: NOR_05_2017_eGISP_Routine

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.

***N. meningitidis* Points of Contact**	Dr. Sancta St. Cyr Dr. Cau Pham	oew3@cdc.gov whi4@cdc.gov	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_2019_Nm

3.1.2.5. Sentinel Site Assignment of Person and Specimen Identifiers

GISP

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 2019 in Columbus will be given the number COL-201901-20. The GISP ID must be maintained for at least the first 25 male gonococcal urethritis isolates.

eGISP

In addition to GISP activities, sentinel sites participating in eGISP 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 isolates collected, including isolates that are identified as possible *N. meningitidis*, eGISP sites should assign and maintain a eGISP/SURRG specimen ID[1], constructed using the 3 letter sentinel site code +

[1] 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 and SURRG activities.

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 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-201703-07) 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

Sentinel Site	Sentinel Site Code*
Albuquerque	ALB
Anchorage	ANC
Baltimore	BAL
Birmingham	BHM
Buffalo	BUF
Camden/ Paterson	CAM
Chicago	CHI
Columbus	COL
Dallas	DAL
Denver	DEN
Greensboro	GRB
Honolulu	HON
Indianapolis	IND
Jackson	JAC
Kansas City	KCY
Las Vegas	LVG
Los Angeles	LA1, LA2
Miami	MIA
Milwaukee	MIL
Minneapolis	MIN
New Orleans	NOR
New York City	NYC
Orange County	ORA
Philadelphia	PHI
Phoenix	PHX
Pontiac	PON
Portland	POR
San Diego	SDG
San Francisco	SFO
Seattle	SEA
Tripler Army Medical Center	TRP
Washington D.C.	WDC

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

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. 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 (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 and as part of the clinical/demographic data sent directly to CDC.

Within eGISP, 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 cryovials should be labeled using the eGISP/SURRG specimen ID**.** See *3.1.2.2. Sentinel Site Laboratory Handling.*

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 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.

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 jurisdiction. 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 ≥ 0.125 µg/ml

Cefixime MIC ≥ 0.25 µg/ml

Azithromycin MIC ≥ 2.0 µg/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. Reporting Clinical and Demographic Data

Clinical and demographic data should be submitted for each patient from whom a GISP and/or eGISP 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 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 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.

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 sentinel sites)**
- eGISP/SURRG ID **(only required for eGISP 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 sentinel sites)**
- Nucleic acid amplification test (NAAT) result **(only required for eGISP 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, if recommended dual therapy administered)
- Secondary treatment for gonorrhea (such as azithromycin 1 g, if recommended dual therapy administered; This variable was previously considered co-treatment for presumed chlamydia, if present)
- Meningococcal vaccination history **(only required for eGISP sentinel sites)**
- Possible *Neisseria meningitidis* isolate **(only required for eGISP sentinel sites participating in the optional activity)**

3.1.3.3. 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_2020_GISP_Epi.xls

GISP/eGISP example: NOR_05_2020_eGISP_Epi.xls

3.1.3.4. Annual Process Measure 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 the Annual Progress Report (APR).

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

- Number of cases of gonococcal urethritis that are diagnosed in men attending the participating clinic
- Number of isolates that are submitted to the assigned GISP regional laboratory
- Percentage of submitted isolates that are found by the GISP regional laboratory to be non-viable or contaminated
- Percentage of monthly isolate batches that are shipped to the GISP regional laboratory within one week after the end of monthly collection
- Percentage of monthly demographic/clinical data transmissions that are submitted to CDC within one month of the completion of specimen collection
- 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.

<u>At a minimum, eGISP awardees are expected to monitor and report on the following measures:</u>

- 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

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 ß-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, and Texas Department of State Health Services 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*

ARLN Laboratory	GISP only sites	GISP/eGISP sites
Texas Department of State Health Services Laboratory	Albuquerque; Dallas; Denver; Jackson	Las Vegas; New Orleans; 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; Greensboro; Indianapolis; Kansas City; Miami; Milwaukee; Minneapolis	Chicago; Pontiac
Maryland Public Health Laboratory	Baltimore; Camden/ Paterson; New York City; Washington D.C.	Columbus; Philadelphia

*ARLN laboratory assignments 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 (β)-Lactamase Activity Assay

The Nitrocefin test will be used to assess the isolates for β-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 β-lactamase.

See Supplement: A Collection of Protocols and Expectations for the CDC *Neisseria gonorrhoeae* Regional

Antimicrobial Resistance Lab Network Chapter 6, Section 10: "β-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 µg/ml	MIC $\geq$ 0.5 µg/ml
Cefixime	MIC $\geq$ 0.25 µg/ml	MIC $\geq$ 1.0 µg/ml
Azithromycin	MIC $\geq$ 2.0 µg/ml	MIC $\geq$ 16 µg/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 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 Management Branch (SDMB) and Laboratory Reference & Research Branch (LRRB) perform the administrative duties and technical assistance responsibilities relating to GISP and eGISP. (See Chapter 6. *Contact Information and Mailing Addresses*)

3.3.1. Description of DSTDP SDMB 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 or both GISP/eGISP on a per request basis.
7. Prepare and distribute an annual report summarizing project findings.
8. Request GISP and eGISP 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 clinical, demographic, and laboratory data with *N. meniingitidis* isolates
12. Assist with data management and annual reports regarding data related to *N. meningitidis* isolates

3.3.2. Description of DSTDP LRRB 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 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 LRRB.
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 ≥0.25 µg/ml, ceftriaxone MICs ≥0.125 µg/ml, or azithromycin MICs ≥2.0 µg/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. Coordinate annual meeting with GC AR Lab Network members at CDC, in collaboration with the Association of Public Health Laboratories (APHL).
13. Provide WGS protocols and technical support to GC AR Lab Network lab staff.
14. Monitor isolate flow, sequence selection and sequencing capacity throughout the GC AR Lab Network in order to ensure timely sequencing.
15. Ensure data is accurately transferred between GC AR Lab Network and CDC DSTDP.
16. 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 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 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 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 December 2016 and both projects 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 data widely available, CDC publishes GISP/eGISP data in annual GISP/eGISP 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 data is encouraged. Sentinel sites can develop conference abstracts and manuscripts for

peer-reviewed publication based on local GISP/eGISP 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 Laboratory Reference & Research Branch (LRRB), *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 CAM= Camden/ Paterson CHI=Chicago COL=Columbus DAL=Dallas DEN=Denver GRB=Greensboro HON=Honolulu IND=Indianapolis JAC= Jackson KCY=Kansas City LVG=Las Vegas LA1/LA2=Los Angeles MIA=Miami MIL=Milwaukee MIN=Minneapolis NOR=New Orleans NYC= New York City ORA=Orange County PHI=Philadelphia PHX=Phoenix PON=Pontiac POR=Portland SDG=San Diego SEA= Seattle SFO=San Francisco TRP=Tripler WDC= Washington, DC	

Variable Name	Type/Length	Description	Values	Comments
CLINID	[Char, 1]	Clinic identifier number	1, 2, 3…9	For Sentinel Sites using more than one clinic to 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.
GISP_SPEC_ID	[Char, 13]	GISP ID	e.g., NYC-201703-07	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.
PATIENT_GENDER	[Char, 1]	Patient Gender	1=male 2=female 3=trans male 4=trans female 5=non-binary/trans other 9=unknown	
ETHNIC	[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, *note that race and ethnicity are not mutually exclusive variables*. 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

Variable Name	Type/Length	Description	Values	Comments
				patient is described as "Hispanic" with no accompanying race data, please code "1" for ethnicity.
AMIND	[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. **Self-reported race status is considered to be the most valid**. 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.
ASIAN	[Char, 1]	Asian	1=yes, 2=no, 9=unknown	
BLACK	[Char, 1]	Black	1=yes, 2=no, 9=unknown	
NAHAW	[Char, 1]	Native Hawaiian/ Pacific Islander	1=yes, 2=no, 9=unknown	
WHITE	[Char, 1]	White	1=yes, 2=no, 9=unknown	
ORACE	[Char, 1]	Other race	1=yes, 2=no, 9=unknown	
DATEVIS	[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.
AGE	[Num, 2]	Age in years	1, 2, 3…98 99=unknown	
CISFEM	[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. 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
CISMALE	[Char, 1]	Cis male partners	1=yes, 2=no, 9=unknown	
TRANSFEM	[Char, 1]	Trans female partners	1=yes, 2=no, 9=unknown	
TRANSMALE	[Char, 1]	Trans male	1=yes, 2=no, 9=unknown	

Variable Name	Type/Length	Description	Values	Comments
		partners		gender)" categories that apply. In clinics where sex or gender of sex partner is not directly ascertained from the patient, code "9" for "unknown" in the cis and trans partner categories.
UNKFEM	[Char, 1]	Female partners (unknown gender)	1=yes, 2=no, 9=unknown	
UNKMALE	[Char, 1]	Male partners (unknown gender)	1=yes, 2=no, 9=unknown	
SYMP	[Char, 1]	Presence of gonorrhea symptom(s) at anatomic site of isolate	1=symptoms present 2=no symptoms present 9=unknown	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: - Urethral infection: urethral discharge and/or dysuria (pain with urination) - Endocervical infection: vaginal discharge and/or dysuria - Rectal infection: rectal discharge, rectal pain, and/or tenesmus (pain with passing bowel movements) - Pharyngeal infection: sore throat 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."
HISTORY	[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."
EPSDS	[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.
HIVSTAT	[Char, 1]	HIV status at time	1=positive	Enter patient's HIV status as known at the time of

Variable Name	Type/Length	Description	Values	Comments
		of clinic visit for gonorrhea	2=negative 3=indeterminate 9=unknown	the clinic visit for gonorrhea. Code "1" for "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.
TRAVEL	[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."
SEXWK	[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.
ANTIBIOT	[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)	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.

Variable Name	Type/Length	Description	Values	Comments
			400 mg 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) 88=other (please indicate in Other Treatment 1) 99=unknown	
OTHTRMT1	[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.
TRMT2	[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	In many cases, two antibiotics may be prescribed for patients diagnosed with gonorrhea. Dual therapy (treatment with a cephalosporin antibiotic and either azithromycin or doxycycline) has been recommended for treatment of gonorrhea since 2010. In addition, patients that are diagnosed with and treated for gonorrhea are often treated for chlamydia at the same time. The recommended therapies for chlamydia are doxycycline and azithromycin. Seven-day courses of erythromycin, amoxicillin, levofloxacin, and ofloxacin are alternatives for selected patients. If dual therapy was administered, indicate the second antimicrobial used. If therapy for chlamydia alone was given, indicate this therapy. 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 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 *N. meningitidis*	1=isolate may be *N. meningitidis* 2=isolate has been positively identified as *N. gonorrhoeae*	A possible *N. meningitidis* isolate is considered when an isolate has (i) the growth of typical appearing *N. gonorrhoeae* 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.
NmVacc*	[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 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 Management 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
eGISP/GISP Data Manager	**Alesia B. Harvey** Tel: (404) 639-8196 FAX: (404) 639-8622 E-mail: abj1@cdc.gov
eGISP/GISP Project Coordinator	**Tremeka L. Sanders** Tel: (404) 639-1807 FAX: (404) 639-8610 E-mail: tnr4@cdc.gov
SDMB Surveillance Team Lead	**Elizabeth Torrone, PhD, MSPH** Tel: (404) 639-8948 FAX: (404) 639-8610 E-mail: igf0@cdc.gov
SDMB Branch Chief	**Hillard S. Weinstock, MD, MPH** Tel: (404) 639-2059

FAX: (404) 639-8622

E-mail: hsw2@cdc.gov

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

LRRB Gonorrhea Team Lead **Brian H. Raphael, PhD**

Tel: (404) 639-4292

FAX: (404) 639-2130

Email: elx9@cdc.gov

LRRB Branch Chief **Ellen Kersh, PhD**

Tel: (404) 639-2728

FAX: (404) 639-3976

E-mail: egk6@cdc.gov

Microbiologist **Evelyn Nash, PhD**

Tel: (404) 718-5037

FAX: (404) 639-2130

E-mail: lmq5@cdc.gov

Biologist **Samera Sharpe**

Tel: (404) 639-2875

FAX: (404) 639-2130

E-mail: bpu7@cdc.gov

Laboratory Quality Manager **Carol Bolden**

Tel: (404) 639-5466

FAX: (404) 639-2130

E-mail: 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*:

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

For *Neisseria meningitidis*:

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

6.2 ARLN Project Laboratory Personnel

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

Tennessee Department of Health

Key Contact:

Henrietta D. Hardin | Laboratory Manager

General Bacteriology & Environmental Microbiology

Division of Laboratory Services

4th Floor South

630 Hart Lane, Nashville, TN 37243

Phone: 615-262-6362 FAX: 615-262-6393

Henrietta.Hardin@tn.gov

Shipping Address:

General Bacteriology & Environmental Microbiology

Division of Laboratory Services

4th Floor South

630 Hart Lane, Nashville, TN 37243

Texas Department of State Health

Key Contact:

Chun Wang | Manager, Bacteriology/Parasitology Diagnostic Group

Texas Department of State Health Services

1100 W. 49th Street

Austin, TX 78756

Phone: (512) 776-2552

Fax: (512) 776-7452

Chun.Wang@dshs.state.tx.us

Shipping Address:

Texas Department of State Health Services

Lab, L429

1100 W. 49th Street

Austin, TX 78756

Maryland Dept. of Health and Mental Hygiene

Key Contact:

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

Manager, Public Health Microbiology Laboratories

Maryland Dept. of Health and Mental Hygiene

1770 Ashland Ave., Microbiology Laboratories

Baltimore, MD 21205

Phone: 443-681-3951

david.torpey@maryland.gov

Shipping Address:

Maryland Dept. of Health and Mental Hygiene

Laboratories Administration

1770 Ashland Ave.

Baltimore, MD 21205

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

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
Documents Coming From Sentinel Sites		
Shipping Manifest – *N. gonorrhoeae*	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_2017_GISP_Routine GISP/eGISP example: NOR_05_2017_eGISP_Routine
Shipping Manifest – *N. meningitidis*	sentinel site code_month_year_Nm	eGISP only example: ORA_05_2017_Nm
Clinical and demographic data	sentinel site code_month_year_Epi	GISP only example: POR_05_2017_GISP_Epi.xls GISP/eGISP example: COL_05_2017_eGISP_Epi.xls
Documents Coming From ARLNs		
Aggregate AST Report to Sentinel Sites	3-digit sentinel site code _Month of testing (as 2 digits)_Year of testing (as 4 digits)	IND_03_2018
Alert to Sentinel Site	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_2018_Alert1
Aggregate AST Repot to CDC	GC AR Lab Network State_Month of testing (as 2 digits)_Year of testing (as 4 digits)	MD_03_2018
Alert or Quick-Send to CDC	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_2018_Alert1 WA_03_2018_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_2018_SURRG_Alert_01
Quarterly shipment of Alert isolates	AR Lab Network State_Year_Quarter _Alert	TN_2018_Q2_Alert
Quarterly shipment of WGS isolates	AR Lab Network State_Year_Quarter_WGS	TN_2018_Q1_WGS
Semi-annual shipment of 'susceptible' isolates	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)

GCMountain (TX PHL)

Encrypted FTP:

GCSoutheast (TN PHL)

GCMidAtlantic (MD PHL)

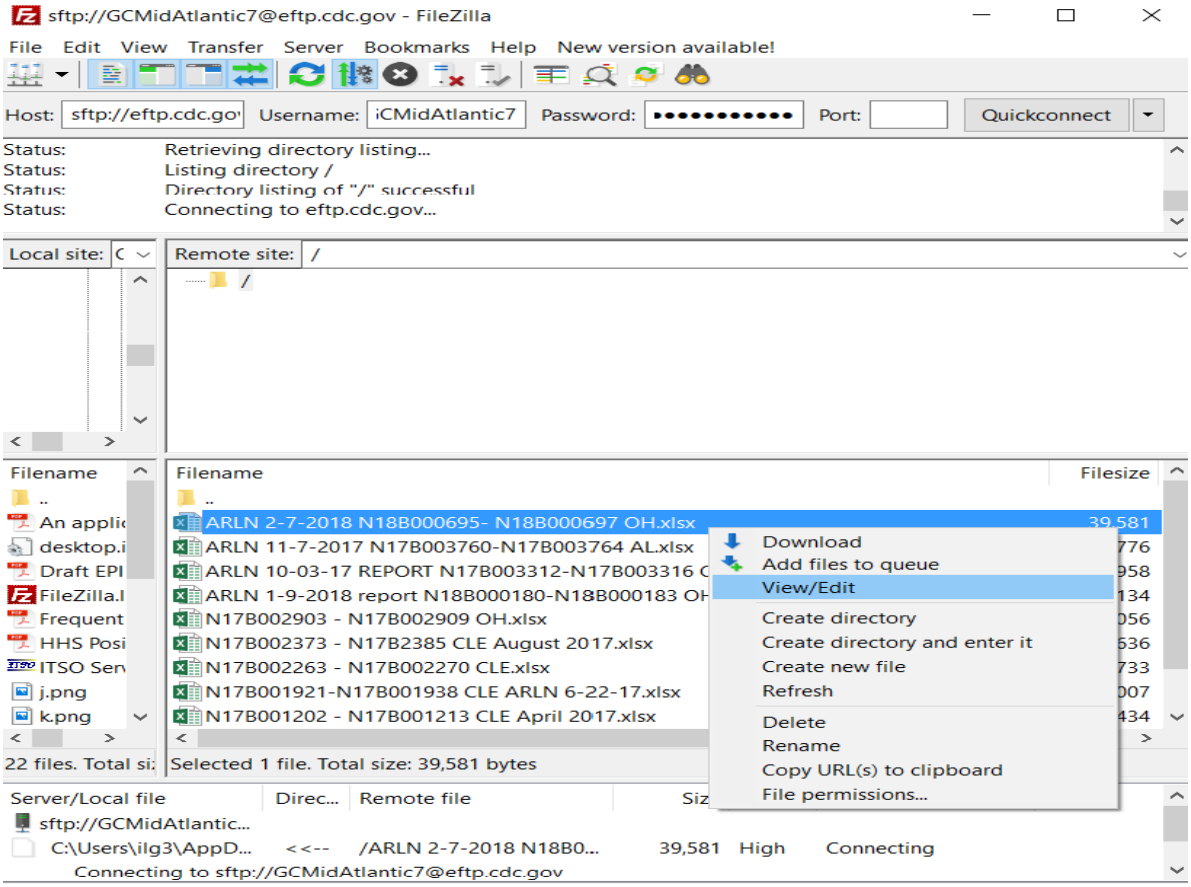
A. Using Filezilla:

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)

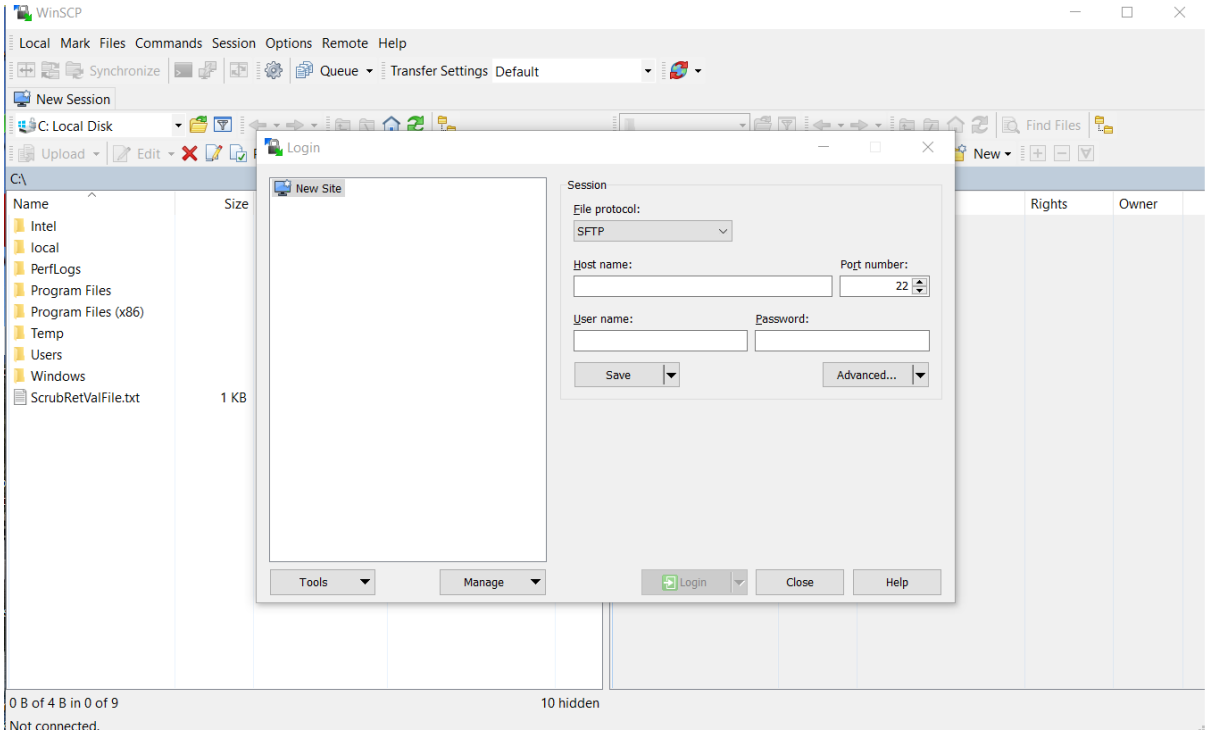
2. To download and save a file to your computer, **right click** on the desired file and select **"View/Edit"**. Once the file opens, you will be able to save it to your computer.

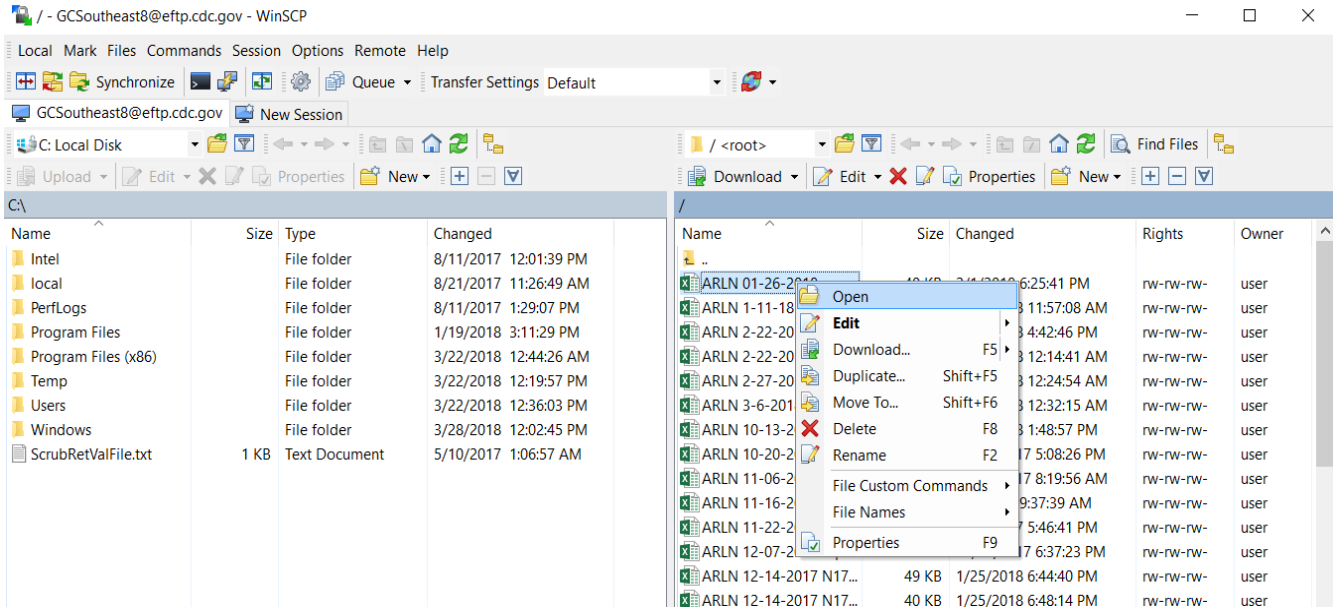


B. Using WinSCP:

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.

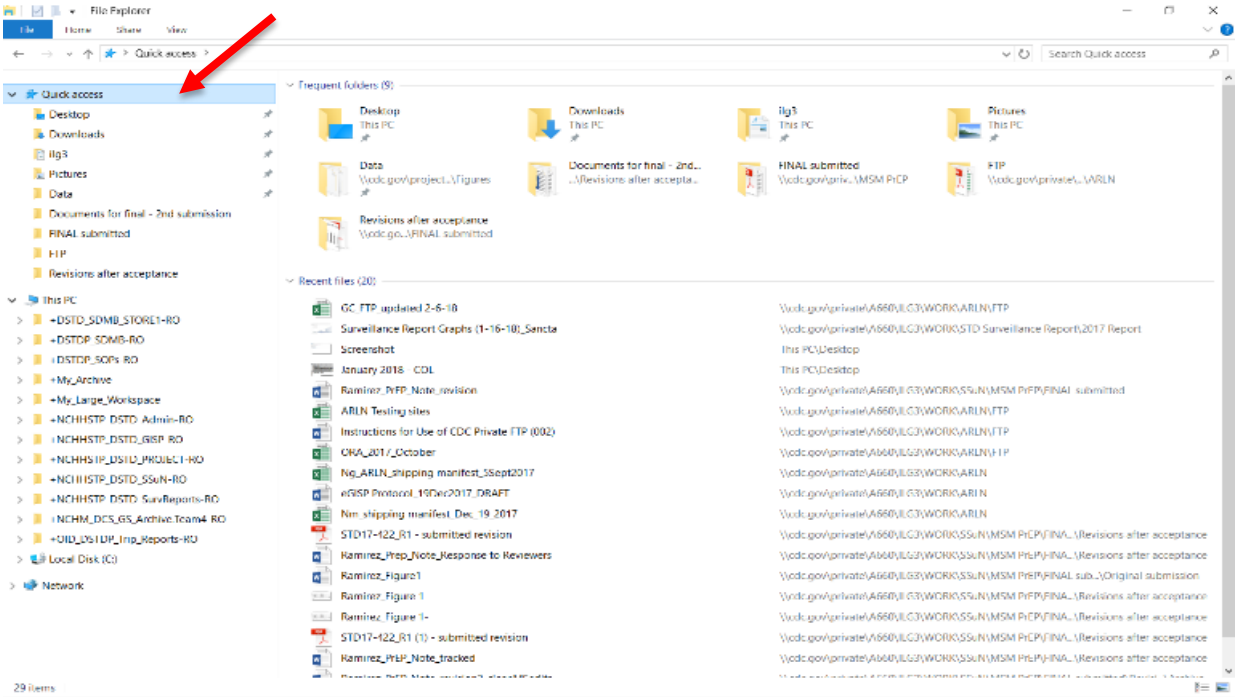




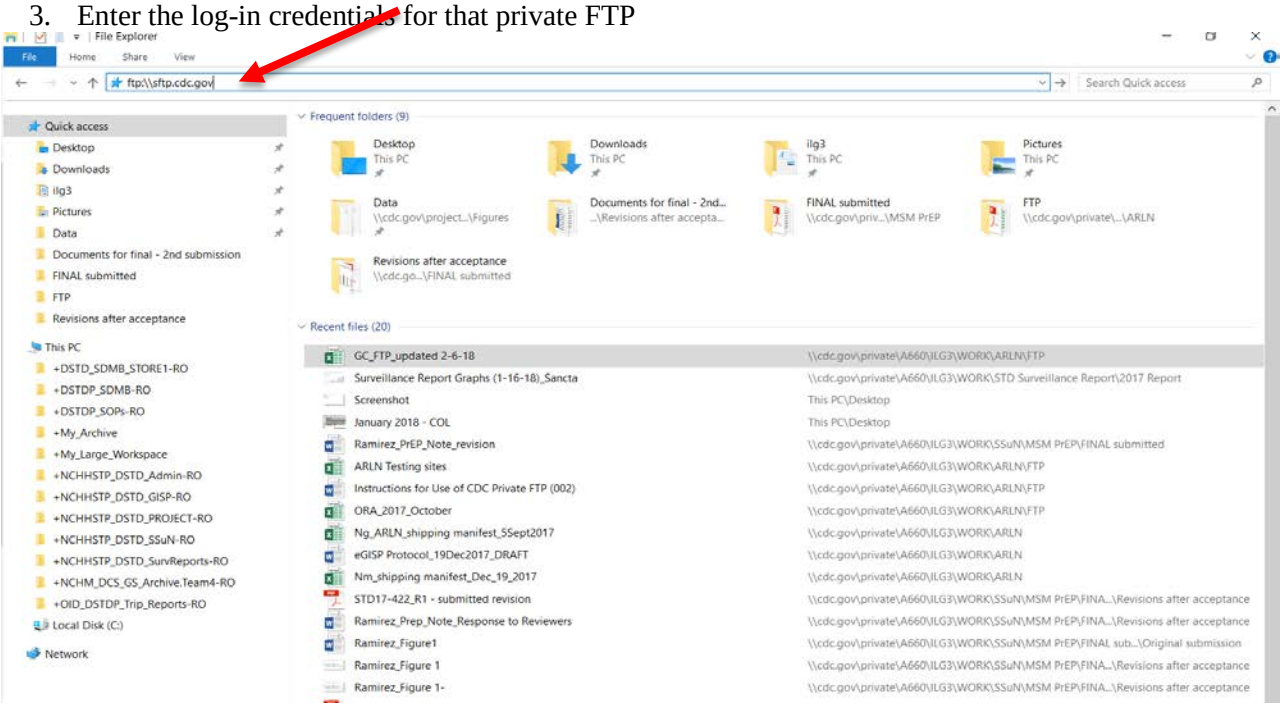
2. To download and save a file to your computer, **right click** on the desired file and select **"Open"**. Once the file opens, you will be able to save it to your computer. You can also select **"Download"** to directly save it to your computer.

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

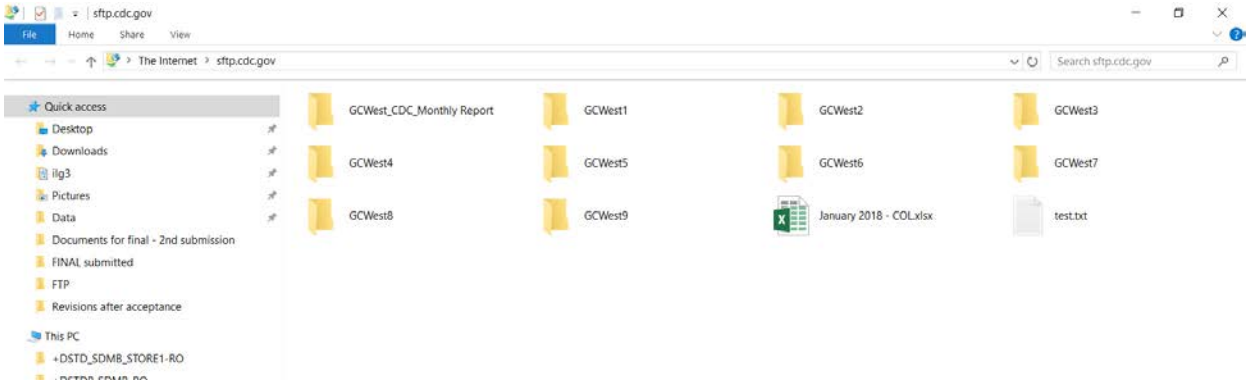
1. First, go to the File Explorer. Click on "**Quick access**".



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

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