DISSEMINATED GONOCOCCAL INFECTION (DGI) GUIDANCE FOR LABORATORIES

Introduction

California has seen an increase in cases of Disseminated Gonococcal Infection (DGI) since July 2020. In order to better understand the DGI increase, the California Department of Public Health (CDPH) is requesting all DGI isolates to be submitted to a public health laboratory for additional testing such as whole genome sequencing and antimicrobial susceptibility testing.

CDPH requests that pure isolates from cases in which *Neisseria gonorrhoeae* is isolated from a disseminated site (such as blood, synovial fluid, cerebrospinal fluid, or skin) be sent to a public health laboratory for further testing and/or to the Centers for Disease Control and Prevention (CDC) for specialized testing as needed.

Specimen Preparation & Submission Instructions



Specimen Submission

Contact your local public health laboratory to notify them of your submission and to obtain routing instructions. Please send pure isolates from DGI cases to your local public health lab using your regular shipping and courier protocols. Your local public health lab can ship specimens to the CDPH Microbial Diseases Laboratory (MDL). Isolates sent to MDL will be forwarded to the CDC for specialized testing as needed. After CDC testing is completed, MDL will return CDC reports to the local public health lab of the patient's residence and/or to the original submitter of the isolate.

Do not submit DGI isolates directly to MDL unless instructed by your local public health laboratory. MDL pre-approval is required for direct submissions to CDC (see detailed instructions below). If you have any questions about this process, please contact the MDL Bacterial Diseases Section (BDS): 510-412-3903.



Specimen Preparation for Transport

We recommend the following steps to maximize the viability of DGI isolates for further public health laboratory testing.

• Step 1: Grow a pure *Neisseria gonorrhoeae* isolate at 35°C in 5% CO₂ on suitable media for gonorrhea (such as chocolate agar or modified Thayer-Martin) for 24-48 hours, until you see visible growth.

- Step 2: Heavily inoculate the media you will use for shipping with your fresh culture. The following three options are recommended:
 - To ship using an agar slant: Heavily inoculate your chocolate (or other suitable media for GC) slant with fresh growth.
 Incubate at 35°C with 5% CO₂ until you see visible growth (18 24 hours is ideal). Then close cap tightly and ship to the public health laboratory at room temperature.
 - To ship using an agar plate: Heavily inoculate your chocolate (or other suitable media for GC) plate with fresh growth. Incubate at 35°C with 5% CO₂ until you see visible growth (18 – 24 hours is ideal). Then seal the plate lid tightly with parafilm and place the plate in zip lock biohazard bag to minimize the risk of the lid coming off during transport. Pack and ship to the public health laboratory at room temperature.
 - To ship using a frozen cryotube with TSB and 15% glycerol:
 Heavily inoculate your cryotube with fresh growth. Immediately place in a -60°C or lower freezer. The isolate will be stable for months-years if it remains frozen. Once the isolate is fully frozen, ship the isolate on dry ice to the public health laboratory.



Specimen Shipment

Ship or courier isolates to your local public health lab, MDL or CDC as instructed within 24 hours of completion of culture preparation for transport. Isolates typically do not need to be shipped directly to CDC unless you require expedited antimicrobial susceptibility testing (within approximately four weeks) and have received MDL pre-approval. MDL will receive a copy of the CDC report once testing is completed. MDL will arrange for CDC reports to be sent to the local public health lab of the patient's residence and/or the original isolate submitter. More specific shipping instructions to MDL and CDC are provided in the section below.

For more information on transportation of gonorrhea isolates, visit: https://www.aphl.org/programs/infectious disease/std/Pages/Ngonorrhoeae-and-C-trachomatis.aspx

Additional Notes:

- Check with your local public health lab for their operating hours and shipping instructions.
- Most local public health laboratories and the MDL are open Monday-Friday. Please time your shipment so it does not arrive on a weekend or holiday.

 In the rare event you need to ship an isolate directly to the CDC, note that the <u>CDC only accepts frozen specimens in cryotubes</u> and does not accept room temperature specimens. Pre-approval from MDL is required for CDC testing. See detailed shipping instructions below.

Remember to ship isolates using the appropriate Department of Transportation / International Air Transport Association approved packaging and shipping procedures.



Consult the STD Control Branch (as needed)

For general questions regarding DGI or this DGI lab protocol, contact the CDPH STD Control Branch DGI project coordinator (<u>lizzete.alvarado@cdph.ca.gov</u>) and Public Health Medical Officer (<u>eric.tang@cdph.ca.gov</u>). For other related questions contact the CDPH STD Control Branch at 510-620-3400.

For laboratory-specific questions regarding DGI isolate preparation, shipping and/or routing, contact your local public health laboratory or CDPH MDL Bacterial Diseases Section at 510-412-3903.

Specific Instructions for Shipping Isolates to CDPH Microbial Diseases Laboratory (MDL)

We recommend submitting DGI isolates to your local public health lab using your regular procedures if possible. However, if your local public health lab prefers that you submit DGI isolates directly to CDPH-MDL, please follow the steps below.

- ✓ Complete the MDL General Electronic Submittal Form available at:

 https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/MDLSubmissionInstruction_sandForms.aspx. For the test requisition option within this form, select "Antimicrobial Susceptibility Testing."
 - a. Indicate that your isolate is from a DGI case in the comments section and provide the minimum four patient and specimen identifiers (name, DOB, specimen collection date, specimen source).
 - b. The patient's home address is REQUIRED to determine county of residence.
- ✓ Follow additional instructions to complete required sections of MDL Form AST Instructions:
 - a. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/MDL-eform-AST-Instructions.aspx. MDL is unable to test or forward specimens with inadequate information.

Submit the specimens and completed submittal form to CDPH MDL. MDL will forward isolates to CDC for specialized testing as needed.

For CDPH/MDL shipping questions, contact Hillary Berman-Watson (hillary.bermanwatson@cdph.ca.gov) or call **510-412-3903**.

Specific Instructions for Shipping Isolates to CDC if expedited Antimicrobial Susceptibility Testing is Indicated

As indicated above, we recommend that labs send their DGI isolates first to their local public health laboratory. In rare cases (i.e., if antimicrobial susceptibility testing is needed within approximately four weeks), your lab may request approval to send a DGI isolate directly to CDC. If this is the case, please follow the steps below for CDC submission:

- ✓ Obtain CDPH-MDL approval by sending an email request to MDL.Submissions@cdph.ca.gov and cc'ing your local public health laboratory.
- Please alert Laura Quilter (lquilter@cdc.gov), Samera Sharpe (bpu7@cdc.gov), and Matthew Schmerer (nmk7@cdc.gov) that you have an isolate available from a DGI case.
- If the antimicrobial susceptibility testing (AST) report is going to be part of the patient's medical record, then please submit the isolate for Etest AST to your state public health laboratory (contact to determine if available) or either the Maryland Department of Health Regional Lab or the Washington Department of Health Regional Lab.
- For routine surveillance AST, please submit the isolate to CDC using test order code 10103 (*Neisseria gonorrhoeae* Study) and include the <u>sample submission form (50.34)</u>. Please include two identifiers for the isolate and do not include PII, if possible, on the 50.34 form.
- Please send the isolate to CDC frozen on dry ice in trypticase soy broth (TSB) with 20% glycerol.
- ☑ The shipping address for our lab at CDC is:

Centers for Disease Control and Prevention RDSB/STAT Unit 31 1600 Clifton Road, NE Atlanta, GA 30333

Telephone: 404.639.4292

☑ Isolates should not be sent on Friday or the day before a federal holiday. We also request that a tracking number be sent to Samera Sharpe (bpu7@cdc.gov) and Matthew Schmerer (nmk7@cdc.gov) to expedite the delivery of the shipment to our laboratory for processing.

Note: Genome sequencing is not a currently validated test for clinical isolates, therefore this will only be performed on isolates submitted for surveillance. Minimal associated data (such as state, specimen type, date of collection, etc.) will be retained. The genome sequencing data will be used to look for various genetic markers and to understand genetic relationships with other isolates recovered from DGI cases.