



# Request for Proposals: Establishing a Quality Control Range for Gentamicin Susceptibility Testing of *Neisseria gonorrhoeae*

Application Due date: May 31, 2019

Submit to: Anne Gaynor, Manager of HIV, viral Hepatitis, STD and TB  
(Anne.Gaynor@aphl.org)

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## Summary

The Association of Public Health Laboratories (APHL), in cooperation with the Centers for Disease Control and Prevention's (CDC) Division of STD Prevention (DSTDP), is seeking to enlist up to nine laboratories to participate in a study to establish the quality control (QC) range for gentamicin susceptibility testing of *Neisseria gonorrhoeae* by the agar dilution antimicrobial susceptibility testing method. Selected laboratories will perform agar dilution to determine the QC range for gentamicin on *Neisseria gonorrhoeae*.

## Background

*Neisseria gonorrhoeae*, causative agent of gonorrhea, is the second most commonly reported notifiable disease in the United States with over half a million cases reported per year. Up to 30% of new infections are reported as resistant to at least one drug currently or previously recommended for treatment. Based on these data and trends, in 2013 the CDC released the first report looking at the burden of antibiotic resistance on human health; [Antibiotic Resistance Threats in the United States](#). The report named antibiotic resistant (AR) gonorrhea among the three most urgent threats leading to a number of reports and development of a national strategy followed by a funded national action plan for Combatting Antibiotic Resistant Bacteria (CARB). Just over a decade ago there were at least five recommended treatment options, in the US today there is only one as *Neisseria gonorrhoeae* is becoming less susceptible to antibiotics recommended for treatment.

One of the aspects of preparing for potential new treatment regimens is ensuring that the diagnostic tools to assess antibiotic susceptibility are in place. Gentamicin is a well-tolerated and inexpensive antibiotic, which, when used in combination with azithromycin, is recommended by CDC to treat uncomplicated gonorrhea in patients with allergies to cephalosporins or in cases of a suspected treatment failure. However, while CDC monitors *N. gonorrhoeae* MIC levels to gentamicin, neither the Clinical Laboratory Standards Institute (CLSI) nor the European Committee on Antimicrobial Susceptibility Testing (EUCAST) have published QC ranges for testing of gentamicin by agar dilution for *N. gonorrhoeae*. These QC ranges are necessary for clinical laboratories to assess the susceptibility level of *N. gonorrhoeae*, and for gentamicin AST data to be used for gonorrhea patient management.

This funding announcement is designed to identify laboratories to participate in a multi-site study to determine the acceptable variability of gentamicin MIC by agar dilution using *N. gonorrhoeae* QC strains leading to a proposed gentamicin QC range for *N. gonorrhoeae* based on CLSI M23 guidelines. There are two options in this RFP. The first option is to serve as a study site and provide gentamicin MIC ranges determined by agar dilution for *N. gonorrhoeae* QC strains. The second option, which is only available to laboratories also applying for option one, is to prepare and distribute antibiotic plates used for agar dilution to other study sites. Please note this is a one-time funding opportunity.

## Eligibility

APHL is looking for nine eligible laboratories, including all member public health, hospital, and academic laboratories with the following capabilities and facilities in place. Applicants may apply for Option 1 Only, or Option 1 and Option 2 but cannot apply for Option 2 only. Specific expectations regarding methodologies to be used by the awardees are outlined in [Appendix A](#): Establishing a Quality Control Range for Gentamicin Susceptibility Testing of *Neisseria gonorrhoeae*. All applicants are required to agree to the minimum requirements (as outlined in [Appendix B](#)) for the option they are applying for. Applicants may apply for Option 1, Option 2, or both.

- 1. Option 1: Provide gentamicin MIC ranges determined by agar dilution for *N. gonorrhoeae* QC strains [9 laboratories requested]**
  - a. Applicants must perform agar dilution for 10 replicates of each of the 3 *N. gonorrhoeae* QC strains on three lots of media containing gentamicin;
  - b. Applicants must perform agar dilution for 10 replicates of each of the 3 *N. gonorrhoeae* QC strains (using the same prepared inoculum) using 1 lot of media containing spectinomycin (control antimicrobial)
  - c. The applicant must be well equipped and with sufficient laboratory space, equipment and workforce capacity for the proposed work.  
Note: Access to a CMI-Promex Steer's Replicator is preferred; CDC can loan appropriate model
  - d. Applicants must conduct testing and provide all data to APHL and CDC prior to the end of the project period.
  
- 2. Option 2: Prepare and distribute antibiotic plates used for agar dilution [2 laboratories requested]**
  - a. Applicants must prepare GC II base plates with 1% Isovitex containing gentamicin or spectinomycin according to CLSI M07 guidelines
    - i. NOTE: CDC will provide all antibiotics and GC II base powder
  - b. Applicants must QC the antibiotic plates and send results to CDC for analysis
    - i. NOTE: CDC will provide the QC isolates required for QC procedure
  - c. Applicants must ship all antibiotic plates overnight to their assigned laboratories within one week of passing QC.
  - d. The applicant must be well equipped and with sufficient laboratory space, equipment and workforce capacity for the proposed work.
  - e. Applicants must agree to conduct testing and provide all data to APHL/CDC prior to the end of project period.

## Anticipated RFP Schedule

April 18, 2019	–	RFP Issued
April 29, 2019	–	Informational Teleconference (Q&A)
<b>May 3, 2019</b>	–	<b>Letter of Intent Due to APHL (see below)</b>
<b>May 31, 2019</b>	–	<b>RFP Responses Due</b>
June 14, 2019	–	Proposal review completed
June 14-17, 2019	–	If needed, follow-up interviews and updated proposals due
June 18, 2019	–	Final review completed and awardees selected
August 1, 2019	–	Draft contracts submitted to APHL Legal Dept. for final internal review

APHL will communicate any modification to this anticipated schedule on APHL's procurement website ([www.aphl.org/rfp](http://www.aphl.org/rfp)) and via an email blast to the public health laboratories (PHLs).

## Response Submittal

### Confirmation of Intent to Respond

Prospective applicants must submit a letter of intent to submit a proposal via email to [Anne.Gaynor@aphl.org](mailto:Anne.Gaynor@aphl.org). APHL must receive the email indicating intent by no later than **5:00pm ET on May 3, 2019**. APHL will not accept a proposal from an applicant that did not submit a letter of intent.

### Final Response

APHL must receive complete responses by **5:00 pm ET on May 31, 2019**. Please see [Proposal-Required Submissions](#) section for items that must be included in the completed proposal. Applicants may send proposals via email to [Anne.Gaynor@aphl.org](mailto:Anne.Gaynor@aphl.org)

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, please email the RFP points of contact above to confirm receipt.

## Award

APHL will select up to nine laboratories to participate in Option 1 and two of the nine laboratories will be selected to participate in Option 2. Each selected applicant for Option 1 will be eligible for an award of \$5,000-\$7,500. Laboratories selected for Option 2 will receive an additional \$15,000-\$20,000 dependent on APHL funding. APHL will distribute the award via a contract administered with APHL.

Please send the Letter of Intent (Due 5/03/19) and completed application (Due 5/31/19) to Anne Gaynor, [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)

## Term of Project

The project term will be from the date of notification through June 30, 2020. The expected contract term will cover the period from September 1, 2019 through June 30, 2020. APHL anticipates that from the date of notification to the start date of the contract, the selected site will work with APHL and the CDC work group to define the sample set, review the proposal, and ensure mechanisms are in place for specimen and data transfer between the participated laboratory and the CDC.

## Evaluation Team

APHL staff, led by the HHST Program Manager, will conduct an initial review of all proposals for completeness. Any incomplete application on the proposal due date specified in the [Anticipated RFP Schedule](#) section above will not be considered and will not receive a formal evaluation.

A team of three subject matter experts (SMEs) from CDC DSTDP and a panel of three APHL members selected from non-applicant public health laboratories will review complete proposals. APHL will identify and select SMEs from CDC based on their familiarity with laboratory techniques and project requirements. APHL member experts will be identified from among the non-applicant PHLs by the APHL HHST Program Manager. They will have expertise in the laboratory testing methods described in this RFP. Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

### Conflict of Interest

APHL will ask potential reviewers to complete and sign APHL's **Conflict of Interest Disclosure Statement** in order to disclose any real or perceived conflict of interest prior to the start of the evaluation process. Reviewers will have to affirm that they have no conflict of interest that would preclude an unbiased and objective review of the proposals received. A copy of the disclosure statement and the related Fiduciary Responsibility and Conflict of Interest Policy is attached as [Appendix D: Conflict of Interest Disclosure Statement and Policy](#). APHL will not select reviewers with a perceived or potential conflict of interest.

## Evaluation Criteria

The evaluation team will evaluate proposals based on responses to the questions in the [Proposal – Required Submissions](#) section and will give a numeric score of up to 100 maximum points based on the scorecard template in [Appendix C](#).

The evaluation team will give preference based on extensive experience with the test methods, ability to handle test volume, ability to comply with expectations laid out in [Appendix A](#), and the ability to meet the minimum expectations outlined in [Appendix B](#).

## Evaluation Process

The evaluation team will conduct the review via a combination of email communication between APHL's HHST Program Manager and the members of the evaluation team, or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL's HHST Program Manager will coordinate the review process and the evaluation sessions.

The reviewers may request follow-up interviews with all or some of the applicant laboratories and, following these interviews, may request supplemental information on an applicant's proposal. The evaluation team will use these interviews and any supplemental information to clarify a laboratory's capacity or experience in one or more of the evaluation criteria, or to explain other information contained in an applicant's proposal.

There will be no formal evaluation performed by a member of APHL staff. In cases where all other evaluation criteria are substantially similar, APHL will have the ability to advise the evaluation team on selections that would provide geographical spread or otherwise diversify APHL's funding allocations. In addition, the evaluation team may receive documentation from APHL staff on an applicant's past performance in other capacities as part of the evaluation criteria.

## Post-Evaluation Procedures

APHL staff will notify the selected laboratories within ten business days of the completion of the evaluation and will post the names of the recipient(s) to APHL's procurement website, [www.aphl.org/rfp](http://www.aphl.org/rfp) on the same day. Unsuccessful applicants will receive notification of these results by e-mail or by U.S. mail within 30 days of the date the name of the selected applicant is posted.

All applicant laboratories are entitled to utilize APHL's RFP Appeals Process to formulate a protest regarding alleged irregularities or improprieties during the procurement process. Specific details of this policy are located on the procurement website.

## Conditions of Award Acceptance

The eligible laboratory must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on behalf of the laboratory. Laboratories must agree to comply with expectations outlined in [Appendix A](#).

The Option 1 eligible laboratory must be able to receive QC agar plates, QC isolates and report results in a timely manner to APHL and CDC. The Option 2 eligible laboratory must also be able to produce and QC agar plates and ship them in a safe and timely manner to other participating laboratories.

Prior to making the official award, a group of individuals from CDC and APHL will be entitled to tour the facilities to assess compliance with requirements for testing and/or have a teleconference with applicant laboratories. Post award, APHL may conduct site visits to include an assessment of continued compliance as necessary.

## Proposal – Required Submissions

In order to be considered for selection, an interested laboratory must submit a proposal that responds to the following questions. Responses should be limited to no more than four double-spaced pages for option 1 only and eight double-spaced pages if applying for option 1 and 2 (font size  $\geq$  11pt and page margins of  $\geq$  1 inch) and must comply with submission requirements set out in the [Additional Information and Deadlines for Application Submission](#) below.

### OPTION 1 REQUIREMENTS:

- 1. Please describe the laboratory's experience with performing agar dilution including addressing the following points.**
  - a. Do you have access to a Steer's Replicator from CMI-Promex Inc.? If so, please specify how many prongs your replicator has (32 or 36)
  - b. Does your laboratory have access to sufficient ancillary equipment, supplies, reagents, and laboratory space to perform agar dilution?
  - c. How many years has agar dilution been performed in your lab?
  - d. How often (times per month) is agar dilution performed?
  - e. Describe the amount of experience and number of staff members trained in agar dilution including: years of experience and consistency in performing agar dilution
  - f. When was the last time the staff performed agar dilution (mm/yyyy)?
  - g. What pathogens are currently tested by agar dilution?
- 2. Please describe the laboratory's experience with other antimicrobial susceptibility tests (AST) other than agar dilution**
  - a. What test methods are performed?
  - b. How often is each test method performed?
  - c. Describe the amount of experience and the number of staff members trained in AST including: years of experience and consistency in performing AST.
  - d. When was the last time the staff performed other AST methods, for each method include date (mm/yyyy)?
  - e. On which pathogens is AST performed?
- 3. Please describe the laboratory's experience in maintaining and preparing *N. gonorrhoeae* culture**
  - a. How often does your laboratory perform tests that require pure *N. gonorrhoeae* culture and what are the tests (e.g. identification, DNA extraction, AST)?
  - b. Describe the amount of experience and the number of staff members trained in preparing and maintaining *N. gonorrhoeae* culture (years of experience).
  - c. When was the last time the staff handled *N. gonorrhoeae* culture (mm/yyyy)?
- 4. Include a completed and signed copy of [Appendix B](#) as an attachment.**

### OPTION 2 REQUIREMENTS

- 1. Please describe the laboratory's capacity to make antibiotic plates**

Please send the Letter of Intent (Due 5/03/19) and completed application (Due 5/31/19) to Anne Gaynor, [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)

- a. Describe the experience and background of the person/people responsible for making antibiotic plates in your laboratory. (media technician vs laboratory technician, years of experience making antibiotic plates used for agar dilution)
  - b. How often does your lab make antibiotic plates used for agar dilution?
  - c. Will designated personnel have allocated time to generate up to 600 antibiotic plates in one week, two times?
  - d. When was the last time the staff prepared plates for agar dilution (mm/yyyy)?
  - e. What antibiotics does your laboratory test when performing agar dilution?
  - f. List any instruments/equipment your lab has for plate preparation.
  - g. Does your laboratory have sufficient supplies, reagents, and laboratory space to make antibiotic plates?
- 2. Please describe the laboratory's capacity to ship antibiotic plates**
- a. Describe how the shipping facilities at your institution could assist in packing and shipping up to 400 agar plates to eight laboratories at 4°C. Include experience packing/shipping fragile, chilled, items in large quantities.
  - b. Describe your laboratory's facilities that can accommodate up to 400 agar plates for 1-2 weeks prior to shipping (walk-in refrigerator, designated space in refrigerator?)
- 3. Include a completed and signed copy of [Appendix B](#) as an attachment.**



## Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Anne Gaynor at [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org). APHL will post questions received from interested PHLs, together with the answers provided by APHL or CDC staff to APHL's procurement website ([www.aphl.org/rfp](http://www.aphl.org/rfp)).

Applicants must submit applications to Anne Gaynor at APHL ([anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org); 8515 Georgia Ave Suite 700, Silver Spring, MD, 20910; telephone: 240-485-2739; fax: 240-485-2700).

**APHL will hold an optional teleconference on Monday April 29 at 3:00pm ET.** The purpose of this call will be to provide a brief overview of the project and to allow potential applicants to ask CDC and APHL questions. Please come with questions prepared.

**Teleconference Call-in Information is below, or please contact [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org) or [infectious.diseases@aphl.org](mailto:infectious.diseases@aphl.org) no later than 12:00pm ET on Monday April 29, 2019 to be sent the calendar invitation.**

Join Zoom Meeting

<https://aphl.zoom.us/j/460352829>

Call-in Information

+1-646-876-9923, Passcode: 460352829# US OR

+1-669-900-6833, Passcode: 460352829# US

**APHL must receive applications, attention Anne Gaynor by close of business (5:00pm ET) May 31, 2019.** Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of each application; if you do not receive an acknowledgement within 48 hours, call 240-485-2739 to confirm receipt.

## **Appendix A: Expectations for Establishing a Quality Control Range for Gentamicin Susceptibility Testing of *Neisseria gonorrhoeae***

### **OPTION 1 METHODS**

Each selected laboratory is expected to perform agar dilution antibiotic susceptibility testing (AST) in accordance with CLSI M07 performance standards and follow the agar dilution SOP provided by CDC.

Testing will be conducted in three stages, with each stage corresponding to one batch of plates prepared with a unique lot of GC base media. Each batch must be tested with all three *N. gonorrhoeae* QC strains using ten uniquely prepared inoculum suspensions. Three to four replicates (from uniquely prepared inoculums) can be tested per day using the same set of antibiotic containing plates. All testing must be completed within three weeks of receiving the antibiotic containing plates.

For the first batch of media, all three QC strains (10 replicates each) will be inoculated onto three sets of plates (3-4 replicates per set) containing gentamicin ranging from 0-64 µg/mL (8 dilutions) and the same inoculum will be used to test plates containing spectinomycin ranging from 1-64 µg/mL (7 dilutions) in parallel as a control (Figure 1). Spectinomycin MIC results must be within the expected MIC range (8-32 µg/mL) for each day of testing gonococcal QC strain ATCC 49226. If the results are not within the expected control range each day of testing, an investigation into the cause of the problem should be conducted (consult with CDC as needed) and the day's testing should be repeated. If the day's testing is being repeated, the original data should be footnoted in the data table. Spectinomycin control testing only needs to be performed on one lot of media, resulting in 30 spectinomycin MIC values reported.

For the second two stages (batches) of testing only gentamicin plates will be tested with the three QC strains and 10 replicates. Labs will test three or four replicates per set of gentamicin plates within three weeks.

Each laboratory will determine colony counts to document the inoculum for each QC strain on each day of testing. Only one replicate's inocula per QC strain needs to be evaluated for colony counts on each day of testing. A minimum of three colony counts are required for each QC strain for each lot of media.

### **OPTION 2 METHODS**

Two laboratories will be selected to make the gentamicin containing agar plates, spectinomycin containing agar plates, and ship the plates to the testing laboratories. Laboratories should follow CLSI M07 standards and the CDC SOP on preparing agar dilution antibiotic plates. The CDC will provide laboratories with GC base powder, gentamicin, and/or spectinomycin. CLSI requires testing on three lots of GC Base media. Therefore, lab A will make two batches of gentamicin containing plates made from Lot 1 and Lot 2 GC Base (Figure 2). Lab B will make spectinomycin containing plates from Lot 1 GC Base and gentamicin containing plates from Lot 3. Each laboratory has one week to make one batch of media. During this week, labs should make 25 sets (25 plates x 7 or 8 dilutions =175 or 200 plates) of drug containing plates per day for two days (175 or 200 plates x 2 days= 350 or 400 plates). One set of gentamicin plates consists of seven doubling dilutions ranging from 1-64 µg/ml (1, 2, 4, 8, 16, 32, and 64 µg/ml) and one control plate with no antibiotic. One set of spectinomycin plates consists of seven doubling dilutions ranging from 1-64 µg/ml. No additional control plates are required.

After each day of media preparation, one full set of drug containing plates needs to be saved for QC. CDC will provide QC strains for the laboratories to perform agar dilution. When performing antimicrobial QC, labs should also assess for sterility on un-inoculated spots. Agar dilution should be performed the week of plate preparation, and MIC results for the QC strains should be sent to the CDC for analysis by the end of the week. Laboratories should ship five sets of plates to each of the eight other testing labs, while keeping five sets for themselves, as soon as possible after the CDC approves of the QC results.

**Figure 1**

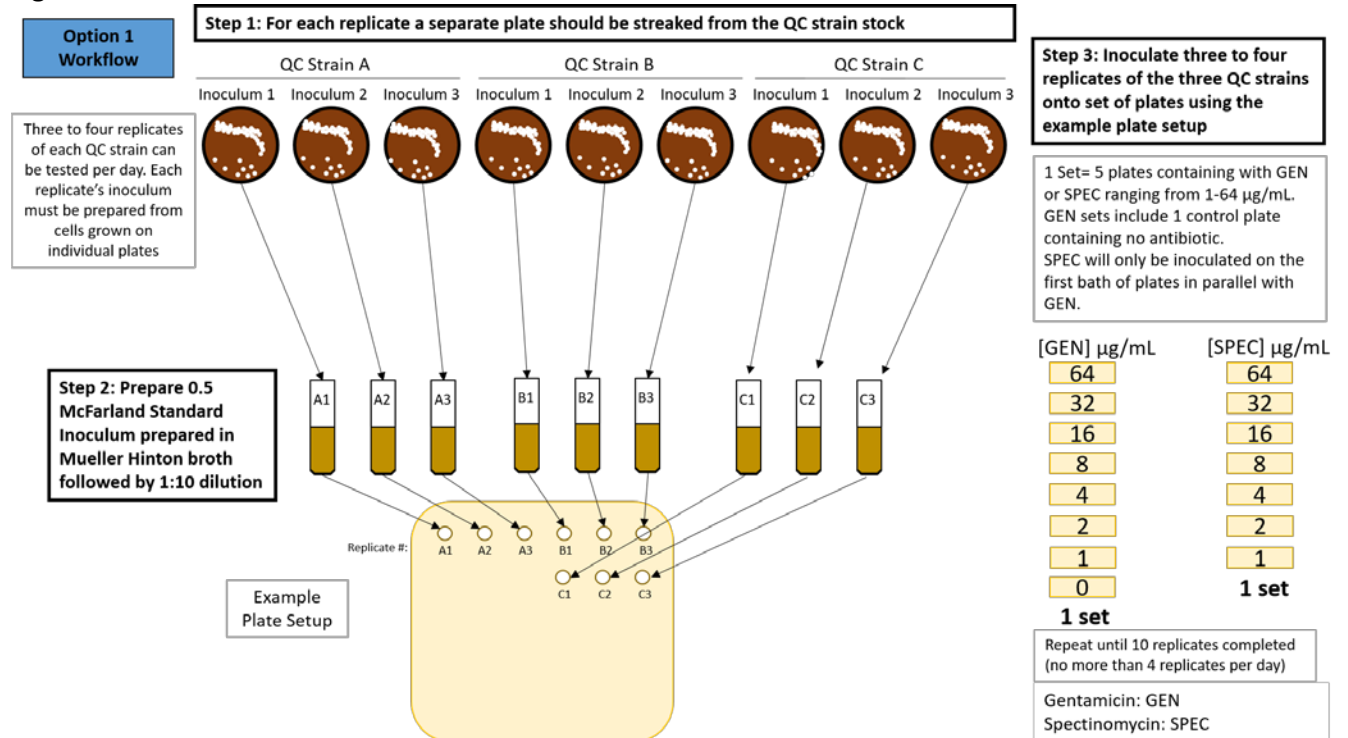


Figure 2

Option 2 Workflow	GC Base Media Lot 1	GC Base Media Lot 2	GC Base Media Lot 3
Lab A	<p><b>Make GEN Plates</b></p> <ul style="list-style-type: none"> <li>Day 1: Make 8 flasks with 0.5 L media- each containing 1 dilution of GEN to obtain 25 plates (20 mL each) at each dilution.</li> <li>Days 2: Repeat to obtain 50 plates at each dilution, 400 total plates</li> <li>Days 3-5: Test one set of plates from each day of preparation for QC and send data to CDC                             <ul style="list-style-type: none"> <li>2 days x 8 dilutions for GEN=16 plates</li> </ul> </li> <li>1 batch of plates: 8 dilutions/set x 5 sets=40</li> </ul>	<p><b>Make GEN Plates</b></p> <ul style="list-style-type: none"> <li>Day 1: Make 8 flasks with 0.5 L media- each containing 1 dilution of GEN to obtain 25 plates (20 mL each) at each dilution.</li> <li>Days 2: Repeat to obtain 50 plates at each dilution, 400 total plates</li> <li>Days 3-5: Test one set of plates from each day of preparation for QC and send data to CDC                             <ul style="list-style-type: none"> <li>2 days x 8 dilutions for GEN=16 plates</li> </ul> </li> <li>1 batch of plates: 8 dilutions/set x 5 sets=40</li> </ul>	<p><b>Do not make plates</b></p>
Lab B	<p><b>Make SPEC Plates</b></p> <ul style="list-style-type: none"> <li>Day 1: Make 7 flasks with 0.5 L media- each containing 1 dilution of SPEC to obtain 25 plates (20 mL each) at each dilution.</li> <li>Days 2: Repeat to obtain 50 plates at each dilution, 350 total plates</li> <li>Days 3-5: Test one set of plates from each day of preparation for QC and send data to CDC                             <ul style="list-style-type: none"> <li>2 days x 7 dilutions for SPEC=14 plates</li> </ul> </li> <li>1 batch of plates: 7 dilutions/set x 5 sets=35</li> </ul>	<p><b>Do not make plates</b></p>	<p><b>Make GEN Plates</b></p> <ul style="list-style-type: none"> <li>Day 1: Make 8 flasks with 0.5 L media- each containing 1 dilution of GEN to obtain 25 plates (20 mL each) at each dilution.</li> <li>Days 2: Repeat to obtain 50 plates at each dilution, 400 total plates</li> <li>Days 3-5: Test one set of plates from each day of preparation for QC and send data to CDC                             <ul style="list-style-type: none"> <li>2 days x 8 dilutions for GEN=16 plates</li> </ul> </li> <li>1 batch of plates: 8 dilutions/set x 5 sets=40</li> </ul>
<p><b>SHIPPING INSTRUCTIONS</b></p> <ul style="list-style-type: none"> <li>Keep 1 batch of plates for testing at your laboratory (GEN=40 plates, SPEC=35 plates)</li> <li>Ship 1 batch of to the other 8 testing sites</li> </ul>			

Gentamicin: GEN  
Spectinomycin: SPEC

### ESTIMATED TIMELINES

While these are only estimated timelines it should be noted that once the plates have been produced and CDC approves the QC by the Option 2 laboratories, the Option 1 laboratories will receive the plates and need to be prepared to conduct all testing for that lot of plates within 3 weeks of receipt. The timing between receipt of Lots 1-3 may be expanded but since the plates are ideally used within 30 days of production Option 1 labs are requested to plan their workload such that all testing can be completed for each lot within that timeframe.

Week	Option 1 Laboratories	Option 2 Laboratories
1		Make Lot 1 Plates (Lab A and B) QC Lot 1 Plates (Lab A and B) Send data to CDC
2	Receive Lot 1 Plates Test Lot 1 Plates (3 replicates)	CDC Approve QC Ship Plates to Testing Sites by Thursday
3	Test Lot 1 Plates (3 replicates) Test Lot 1 Plates (4 replicates)	
4	Test Lot 1 Plates (As needed)	
5		Make Lot 2 Plates (Lab A) QC Lot 2 Plates (Lab A) Send data to CDC
6	Receive Lot 2 Plates Test Lot 2 Plates (3 replicates)	CDC Approve QC Ship Plates to Testing Sites by Thursday
7	Test Lot 2 Plates (3 replicates) Test Lot 2 (4 replicates)	
8	Test Lot 2 Plates (As needed)	
9		Make Lot 3 Plates (Lab B) QC Lot 2 Plates (Lab B) Send data to CDC
10	Receive Lot 3 Plates Test Lot 3 Plates (3 replicates)	CDC Approve QC Ship Plates to Testing Sites by Thursday
11	Test Lot 3 Plates (3 replicates) Test lot 3 Plates (4 replicates)	
12	Test Lot 3 Plates (As needed)	

### Procurement

Supplies, reagents and equipment can be procured using the funding for this project. Funds allocation is at the discretion of the awarded sites.

### Data Management

APHL will provide data collection tables to the awardees. Data will be collected by the sites and sent to APHL and CDC to compile and analyze the results.

### **Performance Management and Evaluation**

Performance will be monitored by timeliness of responses to CDC and APHL requests and successful completion of the testing and reporting.

### **Reports**

The laboratory will submit to APHL and CDC data collection tables after completion of each stage of testing. APHL and CDC will prepare a final report for submission of data to CLSI to propose a new QC range for gentamicin. If a manuscript is developed each awardee laboratory will be offered to add one co-author to the manuscript.

### **Teleconferences**

APHL, CDC and the awardee laboratories will participate in a kick-off teleconference, check-in calls as needed and a final call to wrap-up the study

## Appendix B: Minimum Requirements for Establishing a QC Range for Gentamicin

Please complete the section for the options you are applying for. If you are applying for both, please complete both sections.

### Option 1

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory have experience with AST methods?
		Does your laboratory have experience with <i>N. gonorrhoeae</i> culture?
		Does your laboratory have sufficient ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work?

### Option 2

N/A*	YES	NO	MINIMUM REQUIREMENT
			Does your laboratory have experience with performing agar dilution?
			Does your laboratory have the capability and experience to safely pack and ship up to 600 agar plates?
			Does your laboratory have sufficient ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work?

\*Select N/A if not applying for option 2

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name:

## Appendix C: Establishing a Quality Control Range for Gentamicin Susceptibility Testing of *Neisseria gonorrhoeae*

The following table is a copy of the score card that will be used to evaluate RFP responses.

### Option 1 Score Card:

Category	Maximum Value	Score	Comments (REQUIRED)
<p>1. Does your laboratory have experience performing agar dilution?  <b>Exemplary:</b> Currently performing agar dilution with a CMI-Promex Steer’s Replicator on <i>N. gonorrhoeae</i>; 2 or more staff members are highly experienced in this method (61-70 pts);  <b>Excellent:</b> Currently performing agar dilution on <i>N. gonorrhoeae</i> or performed agar dilution on <i>N. gonorrhoeae</i> in the last 12 months; 2 or more staff members are highly experienced in this method (51-60 pts);  <b>Very High:</b> Performed agar dilution on <i>N. gonorrhoeae</i> within the last 3 years; at least one staff member is highly experienced in this method(41-50 pts);  <b>High:</b> Performed agar dilution on any pathogen within last 3 years; at least one staff member has experience in this method (31-40 pts);  <b>Good:</b> Performs AST using any other method on <i>N. gonorrhoeae</i>; at least one staff member has experience in AST methods (21-30 pts);  <b>Moderate:</b> Performs AST using any other method on any pathogen; at least one staff member has experience in AST methods (11-20 pts);  <b>Limited:</b> Equipment and trained staff are available to conduct AST methods (1-10 pts);  <b>No AST capacity = 0 pts</b></p>	70		Type comments here. (REQUIRED)
<p>2. Does your laboratory have experience with <i>N. gonorrhoeae</i> culture?  <b>Excellent:</b> Currently performs assays (e.g. identification, DNA extraction, AST) on <i>N. gonorrhoeae</i> cultures at least 1x per month and maintains stocks; most staff are highly experienced in <i>N. gonorrhoeae</i> culture (16-20 pts);  <b>Good:</b> Currently performs assays on <i>N. gonorrhoeae</i> culture at least 1x per year and maintains stocks; most staff are experienced in <i>N. gonorrhoeae</i> culture (6-15 pts);  <b>Limited:</b> Not currently maintaining and preparing <i>N. gonorrhoeae</i> culture but laboratory has approved protocols and trained staff in place (1-5 pts);  <b>No <i>N. gonorrhoeae</i> culture capacity = 0 pts</b></p>	20		Type comments here. (REQUIRED)



<p>3. Does your laboratory have sufficient ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work?</p> <p><b>Excellent:</b> Laboratory has dedicated work space and ancillary equipment; lab currently uses the appropriate supplies and reagents, and has approved procedures needed to perform the proposed work (9-10 pts);</p> <p><b>High:</b> Laboratory has an established work space and maintains ancillary equipment; lab currently uses the appropriate supplies and reagents, and has approved procedures needed to perform the proposed work (6-8 pts);</p> <p><b>Moderate:</b> Laboratory has access to shared work space and shared ancillary equipment; lab will purchase appropriate supplies and reagents to perform proposed work (4-5 pts);</p> <p><b>Limited:</b> Laboratory has limited access to shared work space and shared ancillary equipment; lab will purchase appropriate supplies and reagents to perform proposed work (1-3 pts);</p> <p><b>Insufficient equipment, supplies, reagents, space, or workforce= 0 pts</b></p>	10	
<b>TOTAL SCORE</b>	<b>100</b>	— —

Option 2 Score Card:

Category	Maximum Value	Score	Comments (REQUIRED)
<p>1. Does your laboratory have staff with experience in making antibiotic plates?</p> <p><b>Excellent:</b> Laboratory generates antibiotic plates in house regularly (at least once every 3 months); more than one technician is trained on making antibiotic plates (21-30 pts);</p> <p><b>Moderate:</b> Laboratory generates antibiotic plates infrequently for special circumstances; antibiotic plates were made at least once in past 12 months; at least one technician is trained on making antibiotic plates (11-20 pts);</p> <p><b>Limited:</b> Laboratory has materials and approved protocols to generate antibiotic plates; at least one technician is trained on making antibiotic plates (1-10 pts);</p> <p><b>Laboratory does not maintain capacity to generate antibiotic plates; technician(s) require training = 0 pts</b></p>	30		Type comments here. (REQUIRED)
<p>2. Does your laboratory routinely make antibiotic plates for agar dilution?</p> <p><b>Excellent:</b> Laboratory generates antibiotic plates for agar dilution routinely for multiple antibiotics (24-30 pts);</p> <p><b>Good:</b> Laboratory generates antibiotic plates for agar dilution routinely for only a single antibiotic (17-23 pts);</p> <p><b>Moderate:</b> Laboratory generates antibiotic plates for agar dilution infrequently for special circumstances (10-16 pts);</p> <p><b>Limited:</b> Laboratory has materials and approved protocols to generate antibiotic plates for agar dilution (1-9 pts);</p> <p><b>Laboratory does not maintain capacity to make antibiotic plates for agar dilution= 0 pts</b></p>	30		Type comments here. (REQUIRED)
<p>3. Does your laboratory have sufficient ancillary equipment, supplies, reagents, laboratory space, and workforce capacity for the proposed work?</p> <p><b>Excellent:</b> Laboratory has a dedicated media preparation room and ancillary equipment, supplies, reagents, and procedures needed to produce high quality media (16-20 pts);</p> <p><b>High:</b> Laboratory has an established area to prepare media and maintains ancillary equipment, supplies, reagents, and procedures needed to produce high quality media (11-15 pts);</p> <p><b>Moderate:</b> Laboratory has access to shared space used to prepare high quality media (6-10 pts);</p> <p><b>Limited:</b> Laboratory has limited access to shared space used to prepare high quality media (1-5 pts);</p> <p><b>Insufficient equipment, supplies, reagents, space, or workforce= 0 pts</b></p>	20		Type comments here. (REQUIRED)

<p>4. Does your laboratory have sufficient packing and shipping facilities?</p> <p><b>Excellent:</b> Laboratory can utilize highly experienced packing and shipping services who can guarantee the safe delivery of up to 600 agar plates; laboratories have designated refrigerator space to store plates prior to shipping (16-20 pts);</p> <p><b>High:</b> Laboratory personnel are highly experienced at packing agar plates or similar fragile items in bulk and will pack and ship agar plates themselves; laboratories have designated refrigerator space to store plates prior to shipping (11-15 pts);</p> <p><b>Moderate:</b> Shipping facility or laboratory personnel have some experience packing and shipping agar plates or similar fragile items in bulk; laboratories have designated refrigerator space to store plates prior to shipping (6-10 pts);</p> <p><b>Limited:</b> Shipping facility or laboratory personnel have limited experience packing and shipping agar plates or similar fragile items in bulk; laboratory has insufficient space to store plates prior to shipping (1-5 pts);</p> <p><b>Laboratory has no prior experience packing and shipping agar plates or similar fragile items in bulk = 0 pts</b></p>	<p>20</p>	<p>Type comments here. (REQUIRED)</p>
<b>TOTAL SCORE</b>	<b>100</b>	

## **Appendix D: Conflict of Interest Disclosure Statement and Policy**

Association of Public Health Laboratories  
Conflict of Interest Disclosure Statement

**Applicability:** Disclosure of the following information is required of all Officers, Directors, committee members, staff members and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel"). Please answer the following questions and, where indicated, include the same information for your immediate family members (your parents, your spouse or partner, your children and your spouse/partner's parents).

APHL will keep your completed disclosure statement in the corporate records of the association.

1. Please list the name, address, phone number, email address and type of business of your current employer. If you are self-employed, please note that below and provide us with the address, phone number, email address and type of business you operate.

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2. Do you, or does any family member, currently serve as an officer, director, committee member, or other volunteer (or work as an employee of or a paid consultant to) any organization serving the interest of laboratory science or public health laboratories other than APHL or your state or local laboratory?

Yes       No

If yes, please list the organization(s) and provide detail on your or your family member's interest or position in the organization(s).

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3. Do you, or any family member, have an existing or potential interest in, or compensation arrangement with, any third party providing goods or services to APHL, or with which APHL is currently negotiating?

Yes       No

APHL Conflict of Interest Disclosure Statement

If the answer is yes, please provide the name of the organization below and describe in detail the nature of the position held.

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4. Please note any other financial or business interest you may have with any organization serving the interests of public health laboratories.

**If you have none, please check this box:**

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5. Do you, or does any family member, have any other interest or affiliation that is likely to compromise your ability to provide unbiased and undivided loyalty to APHL, or that could come in conflict with your official duties as an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL?

**Yes**       **No**

If you answered yes, please describe in detail below the nature of each such interest or affiliation.

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APHL Conflict of Interest Disclosure Statement

6. If you are currently aware of any actual or possible conflict of interest that might otherwise hamper your ability to serve APHL to your best ability and with the highest degree of care, loyalty and obedience – including any potential conflict you or a family member may have with one or more of the RFP applicants – please describe them in detail below.

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7. Do you agree that so long as you are an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL you will immediately disclose to the other Directors and/or Officers or, for staff members, the Executive Director and/or General Counsel the nature of any interest or affiliation which you may hereafter acquire, which is in or is likely to become in conflict with your official duties with APHL?

Yes       No

**YOU MUST READ THIS SECTION AND THEN SIGN BELOW**

I acknowledge that I have received and read APHL’s Fiduciary Responsibility and Conflict of Interest Policy (the Policy). I have listed all my relevant fiduciary responsibilities and affiliations, and I have identified any actual or potential conflict of interest on this Disclosure Statement and I agree to abide by the Policy. I understand that it is my responsibility to inform APHL in writing of any change in circumstances relating to the Policy and this Disclosure Statement.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

## APHL Fiduciary Responsibility and Conflict of Interest Policy

### 1. Policy Statement and Purpose

The members of the APHL Board of Directors understand the importance of serving APHL to the best of their ability and with the highest degree of obedience, loyalty and care. Accordingly, the Board adopts the following policy for APHL Officers and Directors, all staff, committee members, and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel").

### 2. Individual Duty and Annual Disclosure

APHL Personnel will avoid any conflict of interest with APHL. APHL Personnel will not profit personally from their affiliation with APHL, or favor the interests of themselves, relatives, friends or other affiliated organizations over the interests of APHL. As used in this Policy, "Conflict of interest" includes any actual, apparent, and potential conflict of interest.

Upon commencing service with APHL, each APHL Personnel will file with the Board an annual statement disclosing all material business, financial, and organizational interests and affiliations they or persons close to them have which could be construed as related to the interests of APHL or the profession of public health laboratory science. Each APHL Personnel has an obligation to make an additional disclosure if a conflict of interest arises in the course of the individual's service to APHL, whether arising out of his/her employment, consulting, investments, or any other activity. These disclosures will be documented promptly in writing and recorded in the Board minutes and corporate records.

### 3. Procedure

Whenever APHL considers a matter, which presents an actual, apparent, or potential conflict of interest for APHL Personnel, the interested individual will fully disclose his/her interest in the matter, including the nature, type, and extent of the transaction or situation and the interest of the individual or that individual's relatives, friends or other affiliated organizations. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, what is the appropriate course of action under this policy and the Board vote will be recorded in the minutes.

Any Board member having a conflict of interest must either (i) voluntarily abstain from and be disqualified from participation in all deliberation and voting on all Board actions relating to the situation or matter that gives rise to the conflict of interest, or (ii) ask the Board to determine whether an apparent or potential conflict of interest is considered by the Board to be an actual and material conflict. In the event that the Board member in question requests that the Board evaluate the apparent or potential conflict, that Board member will abstain and be disqualified from participating in (and voting on) the determination of whether the issue presents an actual and material conflict. If the Board determines that an actual and material conflict exists, the Board member in question will abstain from all voting on, and will be disqualified from participation in all deliberation concerning all Board actions relating to the conflict of interest. The vote will be recorded in the minutes.

These procedures will neither prevent the interested individual from briefly stating his/her position on the matter, nor preclude him/her from answering pertinent questions of Board members, since his/her knowledge may be of assistance to the Board's deliberations.

APHL Personnel must be cautious and protective of the assets of APHL and insure that they are used in the pursuit of the mission of APHL. The association's policy requires APHL Personnel to avoid transactions in which APHL personnel may have a significant financial interest in any property which

APHL purchases, or a direct or indirect interest in a supplier, contractor, consultant, or other entity with which APHL does business. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, determine whether the transaction is nonetheless favorable to APHL before considering whether to approve it.

#### **4. Other Duties and Obligations**

Whenever any APHL Personnel discovers an opportunity for business advantage which is relevant to the activities of APHL, the opportunity belongs to APHL and the individual must present this opportunity to the Board. Only once the Board determines not to pursue the matter and relinquishes the opportunity may the individual consider it a matter of possible personal benefit.

APHL Personnel may not accept favors or gifts exceeding \$75.00 from anyone who does business with APHL.

All APHL Personnel will keep confidential those APHL matters designated confidential. APHL Personnel are prohibited from disclosing information about APHL to those who do not have a need to know or whose interest may be adverse to APHL, either inside or outside APHL, and are prohibited from using in any way such information for personal advantage to the detriment of APHL.

All APHL Personnel who participate in APHL activities, including committee activities and international consultation activities, must be adequately prepared to fully participate as their position descriptions require and will do so in accordance with the applicable laws and regulations of their respective state or territory and APHL's Articles of Incorporation, Bylaws, and corporate policies. The APHL Board will read and understand the association's Articles of Incorporation, Bylaws, corporate policies and financial statements, and routinely verify that all state, federal, and local tax payments, registrations and reports have been filed in a timely and accurate manner.

Board members will never exercise authority on behalf of APHL except when acting in meetings with the full Board or the Executive Committee or as authorized by the Board. If any member of the Board has significant doubts about a course of action of the Board, he or she must clearly raise the concern with the Executive Director and the Board and, when appropriate, seek independent expert advice.