Form Approved

OMB No. 0920-0307

Exp. Date xx/xx/XXXX

**Instructions for Quality Control Assessment - Control Strain Susceptibility Testing**

* 1. Quality Control assessment
     1. Quality Control strains:
        1. *N. gonorrhoeae*, strain ATCC 49226 (F-18; Susceptible)
        2. *N. gonorrhoeae*, strain CDC 10328 (intermediate to Ciprofloxacin)
        3. *N. gonorrhoeae*, strain SPL-4 (CMRNG\*, CipHLR\*, CfxDS\*)

\**Abbreviations: CMRNG, strain with chromosomally mediated resistance to penicillin and tetracycline (MICs, ≥2.0 µg/ml); HLR, high-level resistance, MIC ≥16.0 µg/ml of ciprofloxacin; CfxDS, decreased susceptibility to cefixime.*

* + 1. The LRRB will provide one copy (frozen) of each QC strain annually.
    2. ARLN labs are required to propagate and make multiple aliquots of each QC strain upon receiving the isolates.
       1. MICs of QC strains should be confirmed at the time the frozen stocks are prepared.
       2. Make 5 copies/aliquots for each QC strain.
       3. QC strains are stored at -70 oC in a solution of trypticase soy broth containing 20% glycerol.
       4. QC strains may be stored at -70 ºC for up to 2 years.
    3. QC strains propagation
       1. **Do not** **use** QC strain that has been passed more than 10 times.
       2. **Sub**-**culture** QC strains from frozen stock every 7-10 days.

*\*Notes 1: keep the frozen, stock culture(s) on dry-ice (use ice if dry-ice is not available.)*

*\*Notes 2: work quickly to prevent the frozen, stock culture(s) from thawing.*

*\*Notes 3: return the frozen, stock culture(s) to the -70 ºC immediately.*

*\*Notes 4: discard the stock culture if it had been pulled from the -70 ºC more than 10 times.*

* + 1. Quality Control schedule
       1. A QC test is performed each time a new batch of growth medium is made/purchased.
       2. A QC test is performed each time new batch of antimicrobial agent is used.
       3. A QC test is performed each time clinical isolates are tested, unless an Individualized Quality Control Plan (IQCP) is developed that states otherwise.
       4. QC results are recorded on QC form or along with test results.

CDC estimates the average public reporting burden for this collection of information as 5 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).