



CPAL

Central Pennsylvania Alliance Laboratory

# Technical Bulletin

No. 53

September 8, 2005

## Testing algorithm for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

### Starting Date:

September 26, 2005

### Contact:

Dr. Jeffrey Wisotzkey, 717-851-1422

### Explanation:

*Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing is performed at CPAL using the Roche Amplicor® CT/NG Tests. These tests are DNA amplification based assays designed to amplify and detect nucleic acid sequences specific to either *Chlamydia trachomatis* (CT) or *Neisseria gonorrhoeae* (NG) that are present in endocervical swab specimens, male and female urine (See additional notes) and male urethral swab specimens.

Testing yields one of several possible results; a **Positive** result, a **Negative** result or an **Equivocal** result. Each of these results is derived from the test methodology and is a function of specific intensity of a colorimetric reaction that is measured by optical density at wavelength 660nm (OD A<sub>660</sub>). The assay result interpretation depends on the OD A<sub>660</sub> value obtained for each specimen during the performance of the assay. Specific criteria have been established by the manufacturer that defines the OD A<sub>660</sub> and the assay interpretation for each.

Effective September 26, 2005 a change in the testing algorithm will be implemented.

- Specimens that yield a definitively **Positive** *Chlamydia trachomatis* or *Neisseria Gonorrhoeae* result, according to manufacturer's recommended interpretation will be reported as **Positive**, without further testing.
- Specimens that yield a definitively **Negative** *Chlamydia trachomatis* or *Neisseria Gonorrhoeae* result, according to manufacturer's recommended interpretation will be reported as **Negative**, without further testing

Issued on: September 8, 2005

For questions about this and other information, call Central Pennsylvania Alliance Laboratory at 1-888-480-1422.

- Specimens that initially yield an equivocal *Chlamydia trachomatis* result will be referred for testing by a second/alternative method. If the results of the additional testing are positive the result will be reported as **Positive**, if the results of the additional testing are negative, the results will be reported as **Equivocal**, with the comment “Suggest repeat testing in 7 to 10 days, if clinically indicated”.
- Specimens that initially yield an equivocal *Neisseria Gonorrhoeae* result will be subjected to repeat testing (in duplicate) and interpretation per manufacturer’s recommendations. Specimens will be reported as either **Positive** or **Negative**.

On occasion, no result will be reported due to the presence of inhibitory substances or other criteria that rendered the specimen unsuitable for analysis. In these cases a comment will accompany the report that states “Specimen could not be tested due to presence of inhibitory substances. Suggest recollection of specimen”.

**CPAL will no longer routinely send definitively positive *Chlamydia trachomatis* or *Neisseria Gonorrhoeae* specimens for testing by a second/alternate method.**

Physicians that still desire to have positive specimens tested by a second/alternative method may order **CHLAM PLUS** or **GC PLUS** upon specimen submission. If the CT/GC tests are ordered in this manner, specimens that yield a **Positive** result on initial testing will automatically be sent for second/alternative method testing. In this case, all specimens that yield a Positive result by both methods will be reported as **Positive**. Any specimen that is initially positive, but yields a result of Negative using a second/alternate method, will be reported as **Equivocal**.

Additional Notes:

---

- As with any diagnostic test, results from the Roche Amplicor® CT/NG Tests should be interpreted with consideration of all clinical and laboratory findings.
- **The Roche Amplicor® CT/NG Tests is not recommended for evaluation of suspected sexual abuse and for other medico-legal indications.**
- Additional testing is recommended in any circumstance when false positive or false negative results could lead to adverse medical, social or psychological consequences.
- Since the Roche Amplicor® CT/NG Test is not approved for *Neisseria Gonorrhoeae* testing on female urine specimens, these specimens will be sent to a laboratory that utilizes an approved method for this specimen type.