



Region IV & Region VI Bi-regional IPP Meeting  
Lab Subcommittee Agenda & Summary Notes

Subcommittee Chairs:

Jim Gibson, TN DOH  
Erica Pierce, NM DOH

**I. Individual State Testing Data - (use Excel spreadsheet as reference)**

- a. **Test Manufacturer Used**
  - b. **CT/GC versus individual CT or GC**
  - c. **GC Culture**
  - d. **Test Volumes**
  - e. **Specimens tested**
  - f. **Lab Locations**
  - g. **Contracting of Tests**
- Testing methods – An Excel spreadsheet showing the specific test methods and results was prepared for each state. This spreadsheet was distributed so that all states could compare their testing method and results with the other states in the two regions. Arkansas is the only state in Region VI not using GenProbe (using BC Viper).
  - A discussion was held on new test methods and potential changes that may come. Abbott has a new test procedure and so far has only discussed this test with Mississippi. Roche is changing the chemistry of their test and may not be actively marketing their test. Cepheid is working on developing their GeneXpert test to be used in low volume markets where rapid results are needed such as emergency rooms. Their test is self-contained, easy to run, can perform NAAT on multiple organisms, and has results in a few hours. They are marketing it as a moderate complex test and are working to try to get it to a CLIA waived status so non-laboratorians can run it. The cost is around \$35 per test.

**II. Revised Laboratory Testing Guidelines**

- Revised Guidelines – One of the main changes in the revised testing guidelines will be the recommendation that NAAT tests positive results not be repeated. The package insert does not require repeat testing and off-label testing should not be done unless a verification study is done first. In the past several states in Region VI were cited by CLIA for repeat testing. If a state has issues with reproducibility of higher RLU negatives or low RLU positives they should contact their test manufacturer to discuss it. South Carolina is the only state in the group that continues to repeat positive CT and GC tests.

**III. Alternate Specimens (Rectal, Pharyngeal, Self-collected vaginal) and Verification Studies**

- See Miscellaneous Discussions

**IV. Point of Care (POC) Testing**

- See Miscellaneous Discussions

**V. CAP/CLIA Inspection Experiences and Issues**



- CLIA Issues – The group had a discussion of CLIA inspection issues. These included repeat testing, shipping temperatures of CT/GC samples, Roche test specificity, and states changing to CAP instead of CLIA certification. Louisiana is the only state in Region VI not CAP inspected; Kentucky is the only state in Region IV that is CAP inspected.

#### **VI. Economic Issues, Cost Reimbursement, and the Effect on Labs and Testing**

#### **VII. Addressing Health Disparities**

\*Dr. Papp: Input on revised Lab guidelines, POC testing, and new test technology

#### **Miscellaneous Discussions**

- The meeting ended with a general discussion of CT/GC testing issues. These included vaginal swab usage (swab kit should change color to indicate actual collection), Tigris cleaning requirements to maintain stabilization of results, the vaginal swab break line not being distinct and problems this has caused, the need for a clear standard of when multiple anatomical site testing is warranted, LGV testing availability at CDC, varying reimbursement for testing at each state, reimbursement issues, and point-of-care testing (POC). Charlotte Gaydos' Johns Hopkins group is doing a study of POC tests. CDC will also test any GC drug failure specimens that are requested.
- John Papp informed the group about the changing role Rick Steece will play with the CT/GC program. Rick has been assigned to duties to improve the specimen bank for use in verification studies for alternate sites. He will work to make these specimens more readily available and include Abbott, BD and other test manufacturer specimens for verification. Rick will also work on self-collected vaginal swab issues, genital ulcer disease PCR test availability, and be available to coordinate specific issues that states or regions have with Ct/GC testing. Rick will be available to attend Regional meetings when requested to deal with specific issues.