

Quality Assurance of Chlamydia Laboratory Testing

National Chlamydia Laboratory Committee National Infertility Prevention Project (IPP)

All aspects of the testing process must be quality assured to minimize error and to enhance the reliability of test results. Quality assurance includes the pre-analytical and post-analytical stages, in addition to the actual testing procedure.

Written quality assurance procedures for chlamydia testing should be available in each screening laboratory and available to all laboratory staff. Chlamydia laboratory staff should follow approved quality assurance procedures. It is the responsibility of the Laboratory Director of the chlamydia laboratory to ensure that these quality assurance procedures are strictly adhered to throughout the entire testing process.

An essential component of quality assurance is the establishment of specimen rejection criteria to be utilized by the lab staff to determine when and why specimens must be rejected for testing. Rejection criteria give guidance to submitters to help them improve specimen collection and handling at the clinic site.

Prompt laboratory turnaround time (TAT) of lab test results is an important consideration in quality assurance of laboratory performance. Results should be reported to the clinic as rapidly as possible so that immediate follow-up and patient management can be initiated. TAT should be monitored periodically by the laboratory to determine if there are delays in specimen transport to the laboratory, testing and reporting of test results, and delays in reports reaching the clinics. Corrective actions must be taken to resolve barriers to rapid TAT.

Proficiency testing (PT) is a means of external quality control and PT is required of every laboratory approved by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988. PT results may alert a laboratory to problems in test procedures, reagents or technical/clerical errors. PT also can provide some assurance to the lab when performance is acceptable. The College of American Pathologists offers a CMS approved PT program for chlamydia

screening by Nucleic Acid Amplification Tests (NAATs) and Non-Nucleic Acid Amplification Tests.

Another mechanism for external quality assurance is the sharing of split samples among laboratories within a particular region. Variation among labs should not exceed 5 percent disagreement but experience suggests that it will probably be less than 1 percent.

A quality assurance program should include:

- Testing by a CLIA approved laboratory
- Written quality assurance procedures which the lab staff must follow
- Established specimen rejection criteria
- Periodic specimen adequacy evaluation by the lab (Non-NAAT) and follow-up where indicated.
- Acceptable performance demonstrated in an approved PT program
- Adequately trained staff with periodic retraining
- Verification of new or modified test procedures
- Rapid turnaround time of test results, i.e. within 3 working days after specimen received in the laboratory

All components of a quality assurance program must be documented in the records maintained by the laboratory.

It is suggested that one additional quality assurance measure be considered if it is possible for the laboratory to implement:

- Periodic blinded split sample analysis
- Periodic monitoring of specimen TAT (submitter)