

March 2004

Washington State Medical Test Site Rules
PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

GRAM STAINS

TEST COMPLEXITY: **Moderate:**
Endocervical or urethral for GC only; **OR**
As part of the presumptive identification of GC from selective media

High: All other gram stains

PROFICIENCY TESTING: Required

PERSONNEL

- ___ The director, supervisor and testing personnel meet personnel qualifications for moderate or high complexity testing [42 CFR Part 493 subpart M (CLIA) - Available from the LQA Office or online at: www.phppo.cdc.gov/clia/regs/toc.asp]
- ___ Documentation of personnel education, experience, training for the testing performed
- ___ Assessment of personnel competency initially, at 6 months and annually thereafter
- ___ Training is provided to personnel when problems are identified
- ___ Laboratory safety policies are written and staff members adhere to them

QUALITY CONTROL

- ___ Procedures are written which include: specimen collection and handling; preparation of stains; staining procedure; review and interpretation; reporting protocol; quality control; quality assurance
- ___ Have available reference books, atlases to aid in the identification of organisms
- ___ Document the checking of gram stain reagents with positive and negative reference organisms with each new batch of stains and each week of patient testing
- ___ Reagents are properly labeled, stored and used within expiration date
- ___ Microscope maintenance is performed and recorded

QUALITY ASSURANCE

- ___ Policies are written and there is evidence of review of quality control, quality assurance, proficiency testing and patient test results
- ___ Evidence of correlation of gram stain results to culture results (whether done in-house or sent out)

- ___ Policies are written regarding specimen acceptance/rejection
- ___ Policies are written defining critical limits (where applicable)
- ___ Documentation of corrective actions when problems are identified
- ___ Assure that adequate space and facilities are available
- ___ Adhere to local, state and federal regulations for hazardous waste disposal

RECORDKEEPING

- ___ Patient test orders include: patient name or identifier; name and address or identifier of person ordering the test; date and time of specimen collection; source of specimen; patient age (or date of birth) and sex
- ___ Patient test records include: name or identifier; date received; date tested; person who performed the test
- ___ Patient test reports include: name and address of where tests were performed; patient name and unique identifier; date reported; normal ranges; specimen source and limitations
- ___ Records are kept for 2 years of lot numbers and expiration dates of stains, and dates when placed into use
- ___ The following records are maintained for 2 years: Requisitions; test records; reports; quality control; quality assurance; proficiency testing data