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