March 2004 Washington State Medical Test Site Rules

PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

AEROBIC CULTURES FOR THE DETERMINATION OF GROWTH/NO GROWTH, COLOR REACTION ONLY OR URINE COLONY COUNT ONLY

TEST COMPLEXITY: Moderate

PROFICIENCY TESTING / BIANNUAL VERIFICATION OF ACCURACY:

• For all growth/no growth cultures under the subspecialty of Bacteriology, participation in a 5-sample proficiency testing program is **required**. The following are examples:

Selective media for isolation of Neisseria gonorrhea (GC)
Selective media for isolation of gram negative rods from urine
Urine dip paddles

If a colony count is performed in addition to the growth/no growth urine culture, participation in a 2-sample proficiency testing program **or** performance of biannual verification of accuracy is also required.

• For all growth/no growth cultures or color reaction only cultures under the subspecialty of Mycology, participation in a 2-sample proficiency testing program **or** performance of biannual verification of accuracy is required. The following are examples:

Selective media for isolation of yeast
Selective media for isolation of dermatophytes (reading color reaction only)

If the work up is limited to growth/no growth, color reaction only or colony count only, the following requirements are applicable. Any work up beyond this requires adherence to all general and specialty quality control requirements for moderate or high complexity testing.

PERSONNEL

___ The director, supervisor and testing personnel meet personnel qualifications for moderate 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 is performed 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; inoculation of media; incubation requirements; interpretation of results; reporting; referral for additional work up

___ For commercially prepared media (except selective media used to isolate GC), the manufacturer's documentation of QC on media is retained

___ For new lots or shipments of selective media used to isolate GC (i.e., Martin Lewis, Thayer Martin media) OR each new lot of non-commercial media:

_____ Reference (stock) organisms are available to perform media quality control
_____ The following media checks are performed:
  _____Sterility
  _____Ability to support growth of the intended organism(s)
  _____Selectivity, inhibition or biochemical response

___ Documentation of visual check of all media prior to use (for evidence of contamination, drying, cracking, freezing, etc.)

___ Adhere to media manufacturer's specifications for intended use

___ Assure media is used within expiration date and stored at the proper temperature

___ Read and record temperatures daily for incubator, refrigerator

QUALITY ASSURANCE

___ Policies are written and there is evidence of review of quality control, quality assurance, proficiency testing (or biannual verification), and patient test results

___ Policies are written regarding specimen acceptance/rejection

___ Policies are written defining critical limits (as applicable)

___ Evidence of correlation of culture screening results with other test results (as applicable) i.e., urine microscopic, gram stain, final culture report (from reference lab)

___ 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 test; date and time of specimen collection; source of specimen; patient age (or date of birth) and sex

___ Patient test records show: name or identifier; date received; date tested; person who performed the test

___ Patient test records show documentation of the type of media inoculated and the dates and results of each read-out of the culture, including preliminary and final results

___ Patient test reports include: name and address of where tests were performed; patient name and identifier; date reported; normal ranges; specimen source and limitations

___ Records are kept of equipment function checks and maintenance

___ Records are kept for 2 years of lot numbers and expiration dates of culture media, and dates when placed into use

___ The following records are maintained for 2 years: requisitions; test records; reports; quality control; quality assurance; proficiency testing; biannual verification of accuracy data