March 2004

Washington State Medical Test Site Rules

PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

MODERATE COMPLEXITY MICROSCOPIC EXAMINATIONS

Wet mounts (vaginal, cervical, skin or fecal specimens); KOH preps; pinworm preps; Fern tests; post-coital direct exams; urine sediment; nasal smear for granulocytes; and post vasectomy qualitative semen analysis.

TEST COMPLEXITY:

• **PPMP** (Provider-Performed Microscopic Procedures)

When the microscopic tests listed above are performed only by a provider (MD, DO, Dentist, ARNP, Midwife, PA, Naturopath, Podiatrist) and in conjunction with the patient's visit, the tests are categorized as PPMP. Labs licensed as PPMP must adhere to all applicable requirements for moderate complexity testing, but are not subject to routine on-site inspections.

• **MODERATE**

When personnel other than one of the listed providers perform the microscopic tests listed above, they are considered moderate complexity testing. Sites licensed as moderate must adhere to all applicable requirements for moderate complexity testing, and are subject to routine on-site inspections.

PROFICIENCY TESTING REQUIREMENTS:

Participation in a 2-sample proficiency testing program **or** biannual verification of accuracy is required.

The following requirements apply to both PPMP and Moderate complexity microscopic procedures:

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 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 reagents and stains; preparation and examination of slides; interpretation of results; reporting protocol; quality control; quality assurance

___ Have available reference books, atlases to aid in the identification of unknowns

___ Reagents are properly labeled, stored and used within expiration date

___ Microscope, centrifuge maintenance is performed and recorded

QUALITY ASSURANCE

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

___ Evidence of correlation of microscopic exam results with clinical findings or other lab test results (where possible) - i.e., correlation of urine sediment exam results versus results of urine dipstick or urine culture

___ Policies are written regarding specimen acceptance/rejection

___ Policies are written defining critical values (as 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 identifier; date reported; normal ranges; specimen source and limitations

___ Records are kept for 2 years of lot numbers and expiration dates of reagents and 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; and biannual verification of accuracy data