March 2004

Washington State Medical Test Site Rules

PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

MODERATE COMPLEXITY HEMATOLOGY/COAGULATION

SPECIALTY: Hematology
TEST COMPLEXITY: Moderate

Examples of moderate complexity tests:

- Complete blood counts (CBCs)
- Automated differential
- Manual white blood cell (WBC) differential with **no identification of atypical cells**
- Smears for granulocytes (eosinophils)
- Manual reticulocyte count
- Semen analysis for presence or absence of sperm
- Prothrombin time
- Activated partial thromboplastin time (APTT)
- Fibrinogen tests

Refer to a test complexity listing at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

PROFICIENCY TESTING: Required for analytes specified in 42 CFR 493 Subpart H & I
For hematology these "regulated analytes"are:

- Leukocyte count (WBC)
- Cell Identification
- Automated WBC differential
- Manual WBC differential
- Erythrocyte count (RBC)
- Hemoglobin
- Hematocrit
- Platelet count

Coagulation:

- Prothrombin time
- Partial thromboplastin time (APTT)
- Fibrinogen

Biannual verification of accuracy is required for all tests that are not waived or are not on this list.

PERSONNEL

___ The director, technical consultant, clinical consultant and testing personnel meet personnel qualifications for moderate complexity testing [42 CFR 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

___ Documentation that training is provided to personnel when problems are identified

___ Written laboratory safety policies and evidence that staff adhere to them

QUALITY CONTROL

___ Procedures are written for specimen collection and handling, test performance, reporting of results, quality control and quality assurance

___ Technical procedures include principle, specimen required, equipment/reagents needed, directions for performing the test, (including slide preparation and examination), sources of error, interpretation of results (includes criteria for repeating/referring specimens for further review), reporting protocol and references

___ Test kits and reagents are correctly labeled, stored at the proper temperatures and used within expiration dates

___ For moderate complexity hematology, perform two levels of quality control each day of testing

___ For automated coagulation, perform two levels of quality control each 8 hours of testing and each time reagents are changed

___ For manual coagulation, run patient samples and controls in duplicate and run two levels of control each 8 hours of testing and each time reagents are changed

___ Documentation that equipment/ procedure calibration is done upon implementation of the instrument or method, as required by manufacturer and when controls show trends, shifts or are out of limits

___ Worksheets, printouts, tapes are retained for the most recent two years

___ Documentation of new instrument/test validation studies are available

___ Reference ranges established/verified for control materials and documentation available

___ Patient reference ranges available and verified

___ Reference books / atlases available for identification of unknowns

___ Equipment maintenance performed as appropriate and documented

___ Corrective actions documented

___ Documentation that reagents prepared/stored and used at proper temperatures

QUALITY ASSURANCE

___ Written quality assurance plan available

___ Quality assurance policies written and evidence of evaluation and review of quality control results, proficiency testing results, biannual verification of accuracy of tests, quality assurance activities and patient test results available

___ Written policies for how problems identified and complaints handled and instructions for documenting and correcting problems and resolving complaints and any other remedial actions taken

___ Written instructions for specimen collection, handling, preservation and transportation

___ Written criteria for accepting and rejecting specimens

___ Policies written defining critical values, reporting critical results and corrected reports

___ Refer specimens only to a lab with valid medical test site license or meeting equivalent HCFA requirements

___ Procedure for providing clients updates of testing changes that would affect test results or their interpretation

___ Adequate space and facilities available

___ Local, state and federal regulations for infection control, hazardous/infectious waste disposal adhered to and documented

RECORDS

___ 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 and patient age (or date of birth) and sex

___ Test records include date sample received, date tested and identification of person who performed test

___ Test reports include: name and address of where tests were performed, patient name and identifier, date (and time, if appropriate) results reported, unit of measure for each value, specimen source and limitations, and normal ranges

___ Equipment function checks kept 2 years and maintenance records for life of instrument

___ Lot numbers, expiration dates of kits, reagents, controls, calibrators, standards kept 2 years

___ Records kept for 2 years: requisitions, testing records, patient reports of results, quality control results, proficiency testing data; biannual verification of accuracy of tests, quality assurance activities