3/3/04

Washington State Medical Test Site Rules

PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

MODERATE COMPLEXITY CHEMISTRY TESTS

SPECIALTY: Chemistry

SUBSPECIALTIES: Routine Chemistry
Endocrinology
Toxicology
Urinalysis

TEST COMPLEXITY: Moderate

Examples of moderate complexity chemistry tests: Chemistry panels; electrophoresis; drug screening; therapeutic drug monitoring; arterial blood gases; urine test strip by instrument. Refer to the test complexity listing at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

PROFICIENCY TESTING:

Proficiency testing is **required** for analytes specified in 42 CFR Subpart H & I (CLIA). For chemistry these "regulated analytes" are:

Routine Chemistry:
- ALT/GPT
- Albumin
- Alkaline phosphatase
- Amylase
- AST/GOT
- Bilirubin
- Blood gases
- Calcium
- Cholesterol
- Chloride
- Creatine kinase (CK)
- CK isoenzymes
- Creatinine
- Glucose
- HDL cholesterol
- Iron
- Lactate dehydrogenase (LD)
- LD isoenzymes
- Magnesium
- Potassium
- Sodium
- Total protein
- Triglycerides
- Urea nitrogen
- Uric Acid

Endocrinology:
- Cortisol
- Free Thyroxine
- Serum pregnancy (HCG)
- T3 Uptake
- Triiodothyronine
- TSH
- Thyroxine

Toxicology:
- Alcohol, blood
- Blood lead
- Carbamazepine
- Digoxin
- Ethosuximide
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide
- Quinidine
- Theophylline
- Tobramycin
- Valproic acid

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 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, sources of error, interpretation of results, criteria for repeating/referring specimens for further review, reporting protocol and references

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

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

___ Calibration verification performed, using materials at the low, mid and upper limits of reportable range, every 6 months AND when there is a complete change of reagents, major maintenance, and when controls show trends, shifts or are out of limits

___ Worksheets, printouts, tapes available for most recent two years

___ Documentation of new instrument/test validation studies

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

___ Patient reference ranges available and verified

___ Documentation that appropriate quality control has been performed, evaluated for shifts and trends and reviewed (See attached table for specific requirements)

___ Reference books, instrument operator’s and technical manuals available on site

___ 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 (requisitions) 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

___ Patient 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, preventive/unusual maintenance records, quality assurance activities

Subspecialty/Test	Qualitative		Quantitative	
	Control Material	**Frequency**	**Control Material**	**Frequency**
Routine Chemistry	• Positive and negative reference material	• Each day of use	• Two levels of reference material in different concentrations	• Each day of use
Toxicology				
• GC/MS for drug screening	• Analyte-specific control	• With each run of patient specimens	• Analyte-specific control	• With each analytical run
• Urine drug screen	• Positive control containing at least one drug representative of each drug class to be reported; must go through each phase of use including extraction	• With each run of patient specimens		
Urinalysis				
• Non-waived instrument			• Two levels of control material	• Each day of use
• Refractometer for specific gravity			• Calibrate to zero with distilled water • One level of control material	• Each day of use
Blood Gas Analysis			• Two-point calibration and one reference material	• Each 8 hours of testing
			• One-point calibration or one reference material, or • Another calibration and reference material schedule, approved by the department	• Each time patient sample is tested, unless automated instrument internally verifies calibration every 30 minutes
Electrophoresis	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell	• One control containing fractions representative of those routinely reported in patient specimens	• In each electrophoretic cell