

SECTION I: **Good Laboratory Practice Standards**

I. **TESTS (42CFR 493.1252)**

Expected Compliance: 100%

Only the tests listed below may be performed. A test site may not perform any new laboratory test or examination until it has been requested and approved by the Public Health Laboratory Director.

1. Dipstick Urinalysis
2. Urine Pregnancy Tests
3. HemoCue®
4. Wet Preparation/KOH
5. LeadCare II® (Ottawa CHD only)

II. **TEST PROCEDURES (42CFR 493.1252)**

Expected Compliance: 100%

Sec. 493.1252 Standard: Test systems

Test systems must be selected by the laboratory. The testing **must** be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under Sec. 493.1253. The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions. These conditions must be monitored and documented and, if applicable, include the following:

- Water quality.
- Temperature.
- Humidity.
- Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

Reagents, solutions, control materials, calibration materials, and other supplies, appropriate, must be labeled to indicate the following:

- Identity and when significant, titer, strength or concentration
- Storage requirements.
- Preparation and expiration dates.
- Other pertinent information required for proper use.

III. QUALITY CONTROL (42CFR 493.1105.1256)

Expected Compliance: 100%

Sec. 493.1256 Standard: Control procedures

For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process. The laboratory must establish the number, type, and frequency of testing control materials.

The control procedures must--

- Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.
- Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory:

- At least once each day patient specimens are assayed or examined perform the following for—
 - Each quantitative procedure, include two control materials of different concentrations
 - Each qualitative procedure, include a negative and positive control material

Test requiring controls

Pregnancy tests: **2 External controls** (positive/negative) performed monthly and/or change in lot number.

Internal A/NA run with each patient test

Hemoglobin: 1 level (normal) and internal calibrator each day patient testing is done.
Internal calibrator is performed by analyzer.

Lead: 2 levels (high and low) each day patient testing is done.

Record Keeping/Documentation (42CFR 493.1105)

Expected Compliance: 100%

Sec. 493.1105 Standard: Retention requirements

The laboratory must retain its laboratory records including the patient's chart or medical record if used as the test requisition or authorization, for at least **2 years**.

Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

All records must be complete, kept up to date and in legible handwriting. If a mistake in writing is made, a single line should be made to strike through the mistake followed with the individual's initials making the mistake and dated. The use of "white-out" or "ditto" marks on laboratory records is not acceptable.

IV. EQUIPMENT FUNCTION CHECKS (42CFR493.1254)

Expected Compliance: 100%

Sec. 493.1254 Standard: Maintenance and function checks

Equipment function checks are to be performed and documented by the personnel at each test site.

- Refrigerator- check temperature and range twice daily (am and pm) (2-8°C or 35-46°F)
- Freezer- check temperature and range twice daily (am and pm) $\leq 5^{\circ}\text{C} \leq 23^{\circ}\text{F}$
- Temperatures for freezers storing Varicella vaccine $\leq 5^{\circ}\text{F} (\leq -15^{\circ}\text{C})$

CDC Guidelines/Immunizations require temperature of refrigerators and freezers where vaccines are stored to be monitored twice daily. It is recommended that the temperature of these refrigerators and freezers be checked each morning when opening and again before closing the health department. For refrigerators NOT housing vaccines, checking the temperature each morning will meet the requirements.

- Temperature Recorders
- Change temperature chart weekly
- Charts may be ordered from Immunization.
- Any problems with temperature recorders report to Immunization.

V. EQUIPMENT MAINTENANCE AND REPAIR PREVENTATIVE MAINTENANCE (42CFR 493.1254)

Maintenance and repair of equipment is necessary for proper test performance and test result reporting and is the responsibility of the Program Areas or test site Administrators. The action and date must be recorded on the Equipment Maintenance & Repair Log in Section II.

Preventative Maintenance of equipment, as required by the manufacturer, is the responsibility of the County Health Department testing personnel.

For all maintenance, repair, and preventative maintenance, the following shall be documented: Date of repair or maintenance, What was repaired, Repaired by, Model, Serial number, ODH number.

VI. LABELING OF SUPPLIES AND LABORATORY REAGENTS (42CFR 493.1200, 1252)

Expected Compliance: 100%

Reagents, solutions, control materials, calibration materials, and other supplies must be labeled to indicate the following:

- Date received
- Date opened.

VII. SPECIMEN REFERRAL Public Health Lab Specimen (42CFR 493.1242, 1291)

Expected Compliance: 100%

Sec. 493.1242 Standard: Specimen submission, handling, and referral. The laboratory must have an ongoing mechanism for documenting the specimen referral practices.

It is the responsibility of the test site to monitor laboratory testing. The Shipping Manifest meets the CLIA requirements and will be used to track, identify, or retrieve those specimen and reports that are referred to the Public Health Laboratory.

- Patient preparation. (Public Health Laboratory Resource Manual)
- Specimen collection (Public Health Laboratory Resource Manual)
- Specimen labeling, including patient name or unique patient identifier and, when appropriate specimen source. (Public Health Laboratory Resource Manual)
- Specimen storage and preservation. (Public Health Laboratory Resource Manual)
- Conditions for specimen transportation. (Public Health Laboratory Resource Manual)
- Specimen acceptability and rejection. (Public Health Laboratory Resource Manual)

VIII. SPECIMEN REFERRAL TO CONTRACT LABORATORY (42CFR 493.1241, 1242)

Expected Compliance: 98%

These criteria must be followed to assure optimum patient specimen integrity and positive identification throughout the process of specimen collection, referral, testing by Contract Laboratory, and reporting of results to the test site. Use Specimen Referral Log to track these specimens.

Specimen requirements: Specimen requirements (type of Vacutainer™ tube) are listed on each laboratory requisition.

Specimen Identification: Specimen identification must match information on laboratory requisition.

- Patient's name (last and first)
- Test requested (use test code or test name from requisition)
- Date of collection
- Time collected (only when necessary i.e. for glucose 0,1hr, 2hr, etc.)

Laboratory Requisition: The Contract Laboratory requisition must be completed with the following minimum information to meet the CLIA federal regulations for specimen identification and acceptability.

Complete the program specific requisition.

The account number is preprinted on the requisition.

Listed below is the **minimum** information that must be completed on the Contract Laboratory Requisition.

- Patient's Name
- Specimen Type
- Date of Collection
- County Site Number
- Date of Birth
- Sex
- Test Request (marked on menu of tests)
- Source (time, when appropriate)

Additional information may be required depending on the program needs.

**IX. PERSONNEL ASSESSMENT FOR PERFORMANCE OF WET PREPARATION/KOH TESTS
(42CFR 1235, 1236, 1281)**

Expected Compliance: 100%

Sec. 493.1235 Standard: Personnel competency assessment policies

The laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

All personnel performing these tests must be assessed twice a year (every 6 months). Evidence of this assessment must be documented and maintained in Good Laboratory Practice Manual or with Wet Preparation/KOH Log at each test site where the test is performed and be available for future inspections for a minimum of two years. The Laboratory Training and Assessment Checklist form provides a system of evaluating the relationship between the Wet Preparation and KOH procedures employed at each different site. During each assessment the following must be accomplished:

- Satisfactorily perform the test.
- Satisfactorily record test results and all required information.
- Complete the Laboratory Training & Assessment Checklist form.
- File assessment form at each site the test if performed.

**X. DOCUMENTATION OF EDUCATION FOR WET PREPARATION/KOH TESTING
(42CFR 1361, 1365, 1421, 1423)**

Expected Compliance: 100%

The appropriate formal education documentation, from an accredited institution, must be available for review for **all** personnel performing Wet Preparation/KOH testing. The educational documentation must be maintained in Good Laboratory Practice Manual or with Wet Preparation/KOH Log at each test site where the test is performed. College degrees must be in chemical, physical, or biological science or medical technology. **Licenses or vocational training, or professional certificates do not meet CLIA requirements.** The following documentation is acceptable:

- High school transcript (diploma is acceptable if transcript not available from school)
- Associate's degree (diploma is acceptable if transcript not available from school)
- Bachelor's degree (diploma is acceptable if transcript not available from school)
- Master's degree (diploma is acceptable if transcript not available from school)

All physicians performing wet preparations/KOH testing have a copy of their current Oklahoma medical license on file at the test site.

**XI. PERSONNEL QUALIFICATIONS LISTING (PQL) OF TESTING PERSONNEL FOR WET
PREPARATION/KOH
TESTING (42CFR 493.1361, 1445)**

All personnel performing Wet Prep/KOH or other moderate complex testing must be listed on the Personnel Qualifications form. A copy of the form must be maintained in Good Laboratory Practice Manual or with Wet Preparation/KOH Log and be available at each test site with Laboratory Director's signature. A copy of the form must be sent to the Field Laboratory Operations Section of the Public Health Laboratory.

SECTION II: QUALITY ASSURANCE SITE REVIEWS

Quality Assurance Reviews are performed annually or as required at each site.

I. Field Laboratory Consultant (42CFR 493.1409-1413)

The Field Laboratory Consultant from the Public Health Laboratory Service will be the technical consultant for testing and will conduct the Laboratory Quality Assurance Reviews

II. Notification of Test Site for QA Review

The Field Laboratory Consultant will notify each test site in advance by letter and email.

III. Content of QA Site Review (QAR Checklist found in Section I)

The Quality Assurance review will consist of determining compliance of following:

1. Tests performed
2. Quality Control
3. Documentation and record keeping of function checks performed by test site personnel
4. Preventative maintenance, equipment maintenance, repair by testing personnel
5. Labeling and use of supplies and laboratory reagents.
6. Test procedures and training
7. Referral of specimens for testing

Function checks of equipment made by Field Laboratory Consultant:

<u>Equipment</u>	<u>Function</u>
Wholeblood Centrifuge	2400-3600 RPMs
WIC Scales	Accurate within 1% of 5, 10, 15, 20
Refrigerator/Freezer	Temperature within specified range
Single-analyte instruments	Controls within specified range
Remedial Action	Specific actions taken when problems are identified
Thermometers	Accurate when compared to a calibrated thermometer

IV. Quality Assurance Site Report

The Field Laboratory Consultant, through Disease and Prevention and Community Health Services, will provide a report of the Quality Assurance site review to the Administrators and the District Nursing Managers. This

report should also be forwarded to the staff nurses of the test site. Additional copies of the site report may be distributed to specific Program areas. The site report will consist of the following:

- Provide documentation of equipment function checks performed by the Field Laboratory Consultant
- Identify Deficiencies
- Recommend Corrective Actions

V. Test Site's Plan of Correction

After each Quality Assurance Review the test site shall provide a plan of correction within 10 days of the date the test site received the QA Review.

- Each corrective action should be referenced to the appropriate deficiency.
- The plan of correction must be signed by both the County Administrator and the District Nurse Manager.
- The plan of correction must then be mailed, faxed, or electronically sent to:
 - a. Garry L. McKee, Ph.D., MPH, Chief, Public Health Laboratory Service
GarryM@health.ok.gov
 - b. Leslie Billetter, BS, Supervisor, Field Laboratory Operations
LeslieA@health.ok.gov
 - c. Louis Susanto, MS, Consultant, Field Laboratory Operations
LouisAS@health.ok.gov

Public Health Laboratory Service
P.O. Box 24106
Oklahoma City, OK 73124-0106

Phone number: 405-271-5070
Fax number: 405-271-4850

Appendix:

Inspection Check List 10

Site: Code: Date:

Quality Assessment County Health Department Review Checklist
Public Health Laboratory
Field Laboratory Operations Section

TESTS

Test: Wet Preparation/KOH

- Yes No KOH in date (once opened manufacturers expiration).
- Yes No Saline in date. (Daypack expiration date on crimped end).
- Yes No Receiving and open dates on KOH in use.
- Yes No Receiving dates present on KOH in stock.
- Yes No Reagents and supplies stored correctly (RT).
- Yes No Microscope in good working order (check objectives, lens, clean as needed).
- Yes No Microscope cleaning and repair documented on Preventative Maintenance Log.
- Yes No Training and Assessment current for personnel performing testing.
- Yes No Educational documentation on file for all personnel performing testing
- Yes No Personnel Qualifications Listing current for all personnel performing testing.
- Yes No Test reports complete.
- Yes No Reporting guidelines followed.
- Yes No Test report information matches Wet Prep Specimen Log information.
- Yes No Correct site address present on page containing test report.

*Notes and Test reports reviewed:***Test: Hemoglobin**

- Yes No Meter Trax™ in date (once opened, expires in 31 days).
- Yes No Receiving and open dates present on Meter Trax™ in use.
- Yes No Receiving dates present on Meter Trax™ in stock.
- Yes No Cuvettes in date (once opened, expires in 3 months).
- Yes No Receiving and open dates present on cuvettes in use.
- Yes No Receiving dates present on cuvettes in stock.
- Yes No Reagents and supplies stored correctly (RT or 35-46 °F).
- Yes No Meter Trax™ range is correctly entered.
- Yes No Time and date are correctly entered.
- Yes No Analyzer cleaning documented on Preventative Maintenance Log.
- Yes No Repairs documented on Preventative Maintenance Log.

Test: Urinalysis (where applicable)

- Yes No Control strips in date (once opened, manufacturer's expiration date).
- Yes No Receiving and open dates present on control strips.
- Yes No Receiving dates on control strips in stock.
- Yes No Test strips in date (once opened, manufacturer's expiration date).
- Yes No Receiving and open dates present on test strips in use.
- Yes No Receiving dates present on test strips in stock.
- Yes No Reagents and supplies stored correctly (RT).
- Yes No Controls performed monthly

Test: Urine Pregnancy Test

- Yes No Control solutions in date (once opened, expires in 90 days).
- Yes No Receiving and open dates present on control solutions in use.
- Yes No Receiving dates present on control solutions in stock.
- Yes No Test kit in date (once opened, manufacturer's expiration date).
- Yes No Receiving and opening dates present on test kits in use.
- Yes No Receiving dates present on test kits in stock.
- Yes No Reagents and supplies stored correctly (RT or 35-46°F).
- Yes No Correct form used for recording controls/results.
- Yes No Test kit information correctly documented.
- Yes No Control solution information correctly documented.
- Yes No External control results correctly documented.
- Yes No External controls performed monthly/change in lot number.
- Yes No Internal control results documented for each test.
- Yes No Patient ID's used.
- Yes No Patient results documented.
- Yes No Initials of testing personnel documented.
- Yes No Comments/Remedial Action where applicable.

EQUIPMENT

Scales:

Yes No Infant scales accurate $\pm 1\%$.

Yes No Adult scales accurate $\pm 1\%$.

Centrifuge:

Yes No Wholeblood centrifuge RPMs acceptable.

Refrigerator:

Yes No Refrigerator temperatures in range (2-8°C or 35-46°F).

Yes No Refrigerator and freezer temperatures documented am and pm daily.

Yes No Freezer temperatures in range ($\leq (-5)^{\circ}\text{C}$ or $\leq 23^{\circ}\text{F}$).

Yes No Comments/Remedial Action when applicable.

Thermometers/Temperature Recorders:

Yes No Thermometers/temperature recorders accurate when compared to a calibrated thermometer.

Yes No Temperature recorder within acceptable range.

Yes No Temperature recording disc changed weekly.

Yes No Correct paper used for temperature recorder .

Vacutainer/Microtainer Tubes:

Yes No Tubes in date.

Yes No Date received on vacutainers.

Specimen Referral Log:

- Yes No Date lab report received documented.
- Yes No Tracking information documented (test request and where lab sent for testing)

Preventive Maintenance:

- Yes No Documented
- Yes No Comments/Remedial Action

Record Keeping:

- Yes No White out used
- Yes No Ditto marks used
- Yes No Line through with initials
- Yes No Complete date on every line (mm/dd/yy) on all laboratory logs.