Analytic Systems Policy

Purpose: This policy has been developed to meet the Clinical Laboratory Improvement Amendments (CLIA) Condition 493.1250 (Condition Requirements for Analytic Systems)

Principle: As part of the Laboratory's Quality Assessment Program, analytic systems will be monitored and evaluated for its overall quality. Analytic refers to all steps taken during the actual testing of a patient specimen.

1. Procedure Manual

1.1. A written procedures manual for all tests, assays and examinations performed must be available and followed by laboratory personnel. Manufacturer's operating instructions and package inserts are acceptable; however, any modifications in the instructions must be documented in the procedure manual and, as applicable, the modifications must be verified prior to testing of clinical specimens.

1.2. The procedure manual must include the following, when applicable.

1.2.1. Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection;

1.2.2. Microscopic examination, including the detection of inadequately prepared slides;

1.2.3. Step-by-step performance of the procedure, including test calculations and interpretation of results;

1.2.4. Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;

1.2.5. The reportable range for test results for the test system as established or verified;

1.2.6. Control procedures;

1.2.7. Corrective action to take when calibration or control results fail to meet the criteria for acceptability;

1.2.8. Limitations in the test methodology, including interfering substances;

1.2.9. Reference intervals (normal values);

1.2.10. Pertinent literature references;

1.2.11. System for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life-threatening results, or panic, or alert values; and

1.2.12. Description of the course of action to take if a test system becomes inoperable.

1.3. When writing procedures, the "Ohio Department of Health Laboratory Procedure Manual Template" will be utilized. Any deviations from the template will require prior approval by the Laboratory Director.

1.4. Initial procedures and changes in procedures must be approved, signed, and dated by the Laboratory Director before use.

1.5. The laboratory must retain a copy of each procedure with dates of initial use and discontinuance.
- 1.5.1. Discontinued procedures must be clearly labeled as such, taken out of circulation, and filed.
- 1.5.2. Discontinued procedures will be retained for a period of at least 2 years.

2. Test Systems, Equipment, Instruments, Reagents, Materials and Supplies

2.1. Testing must be performed in accordance with the manufacturer's instructions and in a manner that provides test results that fall into the defined performance specifications.

2.2. Laboratory conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting must be monitored. The following conditions will be monitored, if applicable.
- 2.2.1. Water quality;
  - 2.2.1.1. Water quality parameters to be considered include particulate, ionic, and bacterial content; and total organic carbon.
- 2.2.2. Temperature; and
- 2.2.3. Humidity.
- 2.2.4. All data will be recorded, as necessary, and the records will be retained for a period of at least 2 years.

2.3. The testing equipment that can adversely affect patient test results and test reports will be protected from fluctuations and interruptions in electrical current.

2.4. All reagents, solutions, culture media, control materials, calibration materials and other supplies will be appropriately labeled. This includes all secondary, temporary vessels.
- 2.4.1. Upon receipt, the supply must be labeled with date received (does not apply to temporary vessels).
- 2.4.2. Labels are to include the following:
  - 2.4.2.1. Identity;
  - 2.4.2.2. Concentration (as applicable);
  - 2.4.2.3. Storage requirements;

2.4.2.4. Date of preparation;
2.4.2.5. Date of expiration; and
2.4.2.6. Additionally for secondary vessels, the initials of the staff preparing the supply.

2.5. All reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration, have deteriorated, or are of substandard quality.
2.5.1. This applies to supplies for all assays, including non-CLIA assays.

2.6. Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

3. Establishment and Verification of Performance Specifications

3.1. All test systems (incorporated into use after April, 24, 2003) used by the laboratory will be subject to verification or establishment of the performance specifications prior to reporting patient results. Refer to "Establishment and Verification of Performance Specifications Policy".

4. Maintenance and Function Checks

4.1. Maintenance will be performed as defined by the manufacturer and with at least the frequency specified by the manufacturer; or for in-house, commercially-modified test systems, as established by the laboratory to ensure accurate and reliable test results.
4.1.1. This includes each piece of instrumentation being used, including those peripherally involved in patient testing (e.g., incubators, centrifuges, safety cabinets, autoclaves, laboratory information systems computer and devices, and microscopes).
4.1.2. Maintenance includes unscheduled repairs and scheduled preventive maintenance.

4.2. Function checks will be performed as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.
4.2.1. The performance of daily quality control activities may serve as an additional instrument function check.
4.2.2. For instruments that automatically perform function checks and flag problems, the laboratory will document all corrective actions taken in response to the flagged problems.

4.3. The following equipment is annually certified by an outside vendor to ensure operations are within manufacturer specifications. The service and recertification documentation will be retained by the Quality Assurance office.
- 4.3.1. Balances;
- 4.3.2. Biological Safety Cabinets;
- 4.3.3. Centrifuges;
- 4.3.4. Chemical Fume Hoods;
- 4.3.5. Microscopes;
- 4.3.6. Single-channel or multi-channel pipettes; and
- 4.3.7. Other instruments per manufacturer requirements.

4.4. All maintenance and function checks must be documented and retained for a period of at least 2 years.

4.5. Failure in maintenance or function checks
- 4.5.1. Equipment must be repaired and recertified before being put back in service.
- 4.5.2. If the equipment cannot be recertified, it will be taken out of service.

5. Calibration and Calibration Verification Procedures

5.1. Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the reportable range of test results for the test system.

5.2. Calibration procedures must be performed and documented.
- 5.2.1. Calibration must be performed in accordance with the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer.
- 5.2.2. Using the criteria verified or established by the laboratory:
  - 5.2.2.1. The laboratory must use calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and
  - 5.2.2.2. The laboratory must include the number, type and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration.
- 5.2.3. Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

5.3. Calibration verification must be performed and documented.
- 5.3.1. Calibration verification must be performed in accordance with the manufacturer's instructions.

5.3.2. Using the criteria verified or established by the laboratory:
  5.3.2.1. The laboratory must include the number, type and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and
  5.3.2.2. Calibration materials must include a minimal (zero) value, a mid-point, and a maximum value near the upper limit of the range to verify the reportable range of test results for the test system.
5.3.3. Calibration verification must occur at least once every 6 months and whenever any of the following occur:
  5.3.3.1. Complete change of reagents for a procedure is introduced, unless demonstration that changing reagent lot numbers does not affect the range used to report patient test results and control values are not adversely affected by reagent lot number changes;
  5.3.3.2. Major preventative maintenance or replacement of critical parts that may influence test performances;
  5.3.3.3. Control material reflect an unusual trend or shift or are outside the acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem; or
  5.3.3.4. Established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

5.4. All calibration verification documentation will be retained for a period of at least 2 years.

6. Control Procedures

6.1. Each test system must have control procedures that monitor the accuracy and precision of the complete analytic process. See "Test System Quality Control Policy".

7. Comparison of Test Results

7.1. For the same test that uses different methodologies or instruments, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies or instruments.
  7.1.1. For those instruments that are more susceptible to variations, testing more than twice a year may be required.
  7.1.2. The results of the comparison activities will be documented and signed by the Supervisor and Laboratory Director.

7.2. The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available. See individual laboratory section procedure manuals for specific instructions.
  7.2.1. Patient age;
  7.2.2. Sex;
  7.2.3. Diagnosis or pertinent clinical data;
  7.2.4. Distribution of patient test results; or
  7.2.5. Relationship with other test parameters.

8. Corrective Actions

8.1. Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. The laboratory must document all corrective actions taken. See "Corrective Action Policy".

9. Test Records

9.1. All specimens must be properly labeled with a unique identification number to ensure positive patient identification through specimen accessioning and storage, testing and reporting of results.

9.2. Records must indicate the date and time of specimen receipt into the laboratory.

9.3. Records must reflect all the tests and dates of performance of in-house patient testing, including the identity of the personnel that performed the test(s).

9.4. Laboratory records are not documented in pencil and the use of white-out is not acceptable. Manual corrections to test records include the following:
  9.4.1. Place a single line through the incorrect information;
  9.4.2. Write "error" in proximity to the lined out information;
  9.4.3. Initial and date;
  9.4.4. Write "correction" in the proximity to the correct information; and
  9.4.5. Initial and date.

9.5. Records of patient testing including, if applicable, instrument printouts, must be retained for a minimum of 2 years.

10. Quality Assessment of Analytic Systems

10.1. Investigations and corrective actions/improvements will be taken any time an error or potential problem is identified in the any of the above areas.

10.1.1. This correction process involves identification and resolution of the problem and development of procedures, as applicable, that will prevent recurrence.

10.2. In order to ensure quality testing and accurate results, the laboratory will implement, as necessary, continuous improvement activities. The continuous improvement activities may be long-term or short-term assessments. The activities will be developed by the Section Supervisor, Quality Assurance office, and the Laboratory Director.

10.2.1. Continuous improvement activities may include, but are not limited to:

10.2.1.1. Annual review of procedure manuals by section Supervisor or designee for accuracy and content;

10.2.1.2. Development, completion, and review of internal quality assurance audit reports;

10.2.1.3. Review of turnaround time reports; and

10.2.1.3. Management review of completed corrective action documents.

10.3. Efforts to reduce problems associated with analytic systems will be documented, including the use of the "Request for Remedial Action Form" (RFRA), as appropriate.

10.4. On a regular basis, laboratory management will review the laboratory's analytic quality system and all of its activities to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements.

11. References

11.1. CLIA Standard 493.1251; Standard requirements for Procedure Manual

11.2. CLIA Standard 493.1252; Standard requirements Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies

11.3. CLIA Standard 493.1253; Standard requirements for Establishment and Verification of Performance Specifications

11.4. CLIA Standard 493.1254; Standard requirements for Maintenance and Function Checks

11.5. CLIA Standard 493.1255; Standard requirements for Calibration and Calibration Verification Procedures

11.6. CLIA Standard 493.1256; Standard requirements for Control Procedures

11.7. CLIA Standard 493.1281; Standard requirements for Comparison of Test Results

11.8. CLIA Standard 493.1282; Standard requirements for Corrective Actions

11.9. CLIA Standard 493.1283; Standard requirements for Test Records

11.10. CLIA Standard 493.1289; Standard requirements for Analytic Systems Quality Assessment

Signature Approvals

_____ / 11/19/2014
QA Officer Date

_____ / 11/19/2014
Laboratory Director Date