

REFERENCES:

State Operations Manual, Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Table of Contents, (Rev. 166, 02-02-2017)

DEFINITIONS:

Quality Control /Quality Assurance (QC/QA) can be defined as the set of planned and systematic activities focused on providing confidence that quality requirements will be fulfilled. It covers a wide range of matters that influence the quality of a product or service. In a medical laboratory, the quality can be defined as accuracy, reliability, and timeliness of the reported test results (1).

QA is defined as the overall program that ensures that the final results reported by the laboratory are as correct and accurate as possible.

POLICY:

Name of Agency is committed to Quality Assurance. Quality Assurance refers to activities and programs intended to “assure” or promise improvement in quality of care in a defined medical setting or program. It involves assessing or evaluating quality; identifying problems or issues with care delivery and designing quality improvement activities to overcome them; and follow-up monitoring to make sure the activities did what they were supposed to.

All personnel of **Name of Agency** performing any type of laboratory testing must adhere to the Quality Assurance and Quality Control Plan,

PROCEDURES:

A. Negative consequences of laboratory errors:

1. This broad concept applies to any kind of laboratory testing, including diagnostic testing for bacterial meningitis.
2. Inaccurate meningitis diagnostic results can have significant consequences at the patient care or public health level.

3. At the patient care level, errors can lead to:
 - a. Failure to provide proper treatment to the patient.
 - b. Unnecessary treatment, treatment complications, or additional expenses.
 - c. Delay in correct diagnosis.
 - d. Additional and unnecessary diagnostic testing.
4. At a public health level, laboratory errors on the species, serotype or serogroup identification, as well as antibiotic susceptibility profiles, can impact a cornucopia of public health decisions on the following matters:
 - a. Delay in determining when the epidemic threshold has been reached and implementing public health measures.
 - b. Inadequate national control measure recommendations or treatment algorithms.
 - c. Inappropriate choice of antibiotics or vaccines.
5. These consequences result in increased cost in time, personnel effort, other resources, and poor patient outcomes in terms of morbidity and mortality.

B. Quality Assurance guidelines for personnel training

6. Laboratory testing personnel will go through a laboratory orientation (held at the **Location**) prior to performing any patient testing. Testing personnel are required to attend in-service lectures and presentations in the following laboratory areas:
 - a. Specimen collection, labeling, handling, and proper storage prior to testing.
 - b. Patient preparation for laboratory testing.
 - c. Venipuncture, finger-stick, heel-stick, and all in-house laboratory testing procedures.
 - d. Updates to laboratory policies and methodology changes.
 - e. CLIA policies and updates.
7. District laboratory technologists will coordinate with supervisors to schedule laboratory training. The training documentation will be signed by the Lab Director and maintained in the employee's personnel file for at-least two years.

C. GUIDELINES FOR COMPUTER DOWNTIME: LABORATORY

1. Test Request Forms:

- a. When M&M (or electronic system) is not available, providers may request patient laboratory testing by completing an in-house laboratory test request form or a current reference lab requisition form.
- b. Inhouse laboratory test request forms will be maintained in the laboratory until they can be entered into the M&M system and charted.
- c. Original current reference lab requisition forms will accompany the specimen.
- d. Duplicate current reference lab forms will be maintained in the laboratory until they can be entered into the M&M system.

2. In-House Test Result Forms:

- a. Make a copy of the result form: the copy will be given to the ordering provider and the original will be retained in the laboratory to be entered in the M&M system and charted.
- b. Laboratory personnel will calculate the costs of patient testing and escort patients to the check-out desk for payment.
- c. Billing specialists will maintain a roster of patient lab test payments in order to update bills in the M&M system.
- d. Computer labels will be unavailable, so the forms **must** contain the following information:
 - i. Last name, first name, middle initial
 - ii. Date of birth
 - iii. Patient ID number
 - iv. Order date
 - v. Mark required tests
 - vi. Signature of provider
- e. Medicaid/Medicare:

Quality Assurance Procedure

Name of Agency

- i. Same as above
- ii. Medicaid/Medicare number
- iii. Full patient address
- iv. **All** relevant ICD10-CM diagnosis codes

Name

Laboratory Director