

10A NCAC 46 .0216 LABORATORY

A local health department shall provide, contract for the provision of, or certify the availability of public health laboratory services appropriate to the activities of the Department for all individuals within the jurisdiction of the local health department. A local health department shall establish, implement, and maintain written policies which shall include:

- (1) A description of the public health laboratory services provided by the local health department, a copy of a contract for the provision of public health laboratory services, or a certification of availability of public health laboratory services. These public health laboratory services shall include:
 - (a) Clinical tests to aid in the diagnosis and treatment of diseases and conditions.
 - (b) Clinical tests to monitor the response to treatment.
 - (c) Clinical tests to screen for asymptomatic diseases and conditions.
 - (d) Analyses required for environmental activities of the local health department.
- (2) An identification of one person to manage the laboratory services program.
- (3) A description of fees, if any, for public health laboratory services provided by the local health department.
- (4) A standard operating procedures manual which contains standardized protocols and describes quality control requirements for all procedures performed by the local health department.
- (5) An assurance that persons performing tests and analyses have demonstrable skill and competence in achieving accuracy and precision of tests and analyses.
- (6) Provisions for adequate space and facilities.
- (7) A description of the laboratory records system. The system shall include documentation of quality control.
- (8) Provisions for the protection of the safety of staff, patients, clients, and the general public regarding specimen collection, laboratory operations, and disposal of wastes.
- (9) A description of eligibility criteria, if any, for public health laboratory services provided by the local health department.

History Note:

Authority G.S. 130A-9;

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Transferred and Recodified from 10 NCAC 12 .0242 Eff. April 4, 1990;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.