CHAPTER 42 - LABORATORY SERVICES

SUBCHAPTER 42A - GENERAL POLICIES

10A NCAC 42A .0101 SCOPE

The following are the general purposes of the State Laboratory of Public Health:

- (1) This laboratory analyzes specimens and samples for physicians, health clinics, other laboratories and other agencies, (federal, state, local and private) to aid in the diagnosis, treatment and monitoring of individual, community, or environmental health problems.
- (2) It strives to improve the quality and relevance of health related laboratory services performed in the state.
- (3) It provides, at cost, vaccines and other biologicals such as antirabic treatments and kits for the collection and shipment of specimens and samples.

History Note: Authority 130A-88; Eff. February 1, 1976; Readopted Eff. November 15, 1977; Amended Eff. September 1, 1990; October 1, 1985; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 42A .0102 DEFINITIONS

The following definitions shall apply throughout this Chapter:

- (1) "Laboratory" refers to the State Laboratory of Public Health as described in G.S. 130A-88.
- (2) "The laboratory" refers to any other health related laboratories in North Carolina.
- (3) "Specimen" refers to material collected from human beings, animals and insects.
- (4) "Sample" refers to material collected from the environment and includes milk and other food although these may be animal products.
- (5) "CDC" refers to the Centers for Disease Control in Atlanta, Georgia.
- (6) "Authorized sender of specimens" refers to any individual who is authorized to manipulate a patient for the purpose of collecting blood, spinal fluid, and other body materials for analysis, or to an agency such as a hospital, local health department, or clinic which employs persons to perform such services under the direction of a licensed individual, when submitting specimens for types of analyses that have been approved by the Department for submission to the Division or which are required by law or rule to be submitted to the Division.
- (7) "Authorized sender of samples" is any individual who has been designated by law, rules and regulations, or professional position to collect and submit environmental material for analysis when submitting specimens for types of analyses that have been approved by the Department for submission to the Division or which are required by law or rule to be submitted to the Division.
- History Note: Authority G.S. 130A-88; Eff. February 1, 1976; Readopted Eff. November 15, 1977; Amended Eff. September 1, 1990; October 1, 1985; October 1, 1984; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 42A .0103 FORMS

The following types of forms are available from this laboratory:

- (1) Identification forms which must accompany specimens or samples; These request the full name and address of the sender, the name of the patient (if applicable), the source of the specimen or sample, and other specific information necessary for intelligent analysis or for epidemiological data gathering;
- (2) Forms which sender uses in ordering specimen or sample collection kits or biologicals; These forms contain lists of material available, cost of each, and space for sender to indicate quantity ordered;

- (3) Application which must be submitted by any laboratory wishing to be certified under any of the certification programs described in this Chapter;
- (4) Application for Admission to Training Courses includes spaces for applicants name, address, training and experience and name of course;
- (5) Forms for participating laboratories to report the results of analysis of proficiency testing specimens or samples; The forms are designed according to the type of specimen or sample and the complexity of the expected results;
- (6) Forms used by public water systems to contract with this laboratory to perform analyses required by G.S. 130A-311 to 130A-332.

History Note: Authority G.S. 130A-88; Eff. February 1, 1976; Readopted Eff. November 15, 1977; Amended Eff. October 1, 1985; October 1, 1984; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 42A .0104 ACQUIRING SERVICES OF CDC

Unless prior approval has been obtained from the State Laboratory of Public Health and the Centers for Disease Control (CDC), all specimens submitted to CDC must be submitted through this laboratory and the results returned to sender through this laboratory. Applications to CDC training courses for laboratories anywhere in the state must be approved by the person in charge of this laboratory and forwarded to CDC.

History Note: Authority G.S. 130A-88; Eff. February 1, 1976; Readopted Eff. November 15, 1977; Amended Eff. September 1, 1990; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 42A .0105 SUBMITTING SPECIMENS OR SAMPLES AND RECEIVING RESULTS

(a) For specific information on individuals or agencies to whom the services described in this Chapter are available, type of specimen or sample to submit, when and how to collect proper specimen or sample, how to ship specimen or sample, test procedures to request, information to submit with specimen or samples, when to expect results, aid in interpretation of results, persons to contact for information or consultation, location and hours this laboratory is open, order forms for kits and biologicals and their current prices, and other pertinent information, please refer to the "laboratory services" manual which is available to authorized senders of specimens or samples and may be obtained from this laboratory.

(b) Private citizens may submit specimens or samples to this laboratory in only one circumstance, animals or animal heads for rabies examination.

(c) Individuals will be given the results of analysis made on specimens in the circumstances described in (b) of this Rule but in all other instances may receive the results only upon written request of the authorized sender.

(d) Upon request of the person who sends a specimen to this laboratory for testing, copies of the laboratory results may be furnished to another authorized sender. Copies of laboratory results shall also be furnished to the Department's health divisions for follow-up or tracking of communicable diseases or conditions in accordance with applicable laws or rules.

History Note: Authority G.S. 130A-88; Eff. February 1, 1976; Amended Eff. May 1, 1977; Readopted Eff. November 15, 1977; Amended Eff. September 1, 1990; October 1, 1985; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 42A .0106 FEES

(a) Upon request, the State Laboratory of Public Health furnishes to authorized senders of specimens and samples kits and materials for collecting and submitting specimens and samples. The fees for these kits and materials are based on cost and are subject to change as costs change.

(b) Upon request, the State Laboratory of Public Health furnishes, to persons authorized to administer them vaccines and other biologicals such as antirabic treatments. The prices for these are based on cost and cost of shipment and are subject to change as these costs change.

(c) An individual is eligible to receive rabies vaccine and immune globulin without charge for rabies post-exposure treatment when the individual meets all of the following criteria:

- (1) the individual's family income is at or below the federal poverty level in effect on July 1 of each fiscal year as determined by the local health department;
- (2) the individual meets the residency and other requirements set forth in 10A NCAC 45A .0200, except that the individual shall not be eligible for Medicaid or health insurance reimbursement for rabies post-exposure treatment as determined by the local health department; and
- (3) the treatment is recommended by a physician licensed to practice medicine.

(d) The State Laboratory of Public Health provides laboratory analysis services to assist owners and operators of public water systems in complying with the North Carolina Drinking Water Act. These services must be contracted for on a yearly basis and must be paid for in advance. Refunds of prepayments will be made only when:

- (1) The water system ceases to exist as a public water system or merges with a larger water system;
- (2) The water system changes in status from a community to a non-community water system or from a non-community to a community water system;
- (3) There has been an overpayment of fees; or
- (4) The laboratory fails to perform an analysis in accordance with the contract.

(e) Fees for the analysis of public water supplies shall be as follows:

| PARAMETER | FEE |
|------------------------|----------|
| Inorganic Chemistry | \$200.00 |
| Organic Chemistry | \$190.00 |
| Coliform | \$ 20.00 |
| Trihalomethanes | \$ 60.00 |
| Sodium and Corrosivity | \$ 60.00 |
| Radiochemistry: | |
| gross alpha and beta | \$ 50.00 |
| radium 226 | \$ 65.00 |
| radium 228 | \$ 50.00 |
| uranium | \$ 75.00 |
| Any single organic or | |
| inorganic parameter | \$ 15.00 |

History Note: Authority G.S. 130A-5(12); 130A-326; Eff. February 1, 1976; Readopted Eff. November 15, 1977; Amended Eff. February 1, 1991; September 1, 1990; April 1, 1987; Temporary Amendment Eff. August 9, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. January 1, 1994; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

10A NCAC 42A .0107 PAP SMEAR FEES

History Note: Authority G.S. 130A-5; Temporary Adoption Eff. January 1, 2004; Eff. May 1, 2004; Expired Eff. January 1, 2018 pursuant to G.S. 150B-21.3A.