

## SUBCHAPTER 42B - LABORATORY SECTIONS

### 10A NCAC 42B .0101 CANCER CYTOLOGY

*History Note: Authority G.S. 130A-88;  
Eff. October 1, 1985;  
Expired Eff. January 1, 2018 pursuant to G.S. 150B-21.3A.*

### 10A NCAC 42B .0102 NEWBORN SCREENING

(a) The State Laboratory of Public Health will conduct screening for the core conditions listed on the Recommended Uniform Screening Panel developed by the Secretary of the United States Department of Health and Human Services and the Advisory Committee on Heritable Disorders of Newborns and Children (the "RUSP"), which is hereby incorporated by reference, including any subsequent editions and amendments, and available free of charge at <https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html>. Specimens shall be submitted to this laboratory for screening in accordance with the procedures set forth in 10A NCAC 43H .0314.

(b) The process to develop and implement new screening for the conditions described in Paragraph (a) of this Rule shall begin after:

- (1) the screening fee set out in Rule .0108 of this Section is adjusted, as permitted by G.S. 130A-125(c);
- (2) funds exist to acquire instrumentation, equipment, Program supplies, and Program personnel; and
- (3) the Program performs assay validations, implements preventative follow-up interventions, secures necessary infrastructure, and meets all federal, State, and local requirements.

*History Note: Authority G.S. 130A-88; 130A-125;  
Eff. October 1, 1985;  
Amended Eff. September 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017;  
Amended Eff. January 1, 2021.*

### 10A NCAC 42B .0103 ENVIRONMENTAL SCIENCES

(a) This laboratory examines samples of drinking water and other environmental materials for evidence of microbiological, chemical or other contamination. No test will be performed on a sample from an open well or an unprotected spring because such supplies are unsafe to drink regardless of laboratory findings.

(b) This laboratory examines samples for monitoring man-made and natural radiochemical levels in air, water, soil, animal and vegetable material, milk and other foods.

(c) This laboratory examines samples of drinking water, samples from industrial environments and other environmental material for the presence of excess levels of inorganic or organic compounds which are deemed detrimental to human health. Sample containers supplied by this laboratory must be used to collect samples.

*History Note: Authority G.S. 130A-88;  
Eff. October 1, 1985;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.*

### 10A NCAC 42B .0104 LABORATORY IMPROVEMENT

(a) Participation in the proficiency testing offered by this laboratory is mandatory for laboratories certified in milk and for laboratories funded through the federal gonorrhea grant to culture females for gonorrhea. Participation in other proficiency testing or by other laboratories is voluntary.

(b) Formal training courses in laboratory procedures and laboratory management are presented by this laboratory for health related laboratorians in the state. Courses are announced in the bulletin, LABORATORY, and are planned in response to requests and needs demonstrated by proficiency testing results.

(c) The bulletin, LABORATORY, is published quarterly and includes announcements of courses offered and information important to laboratory scientists and managers. The bulletin is available to any health related laboratory.

*History Note:* Authority G.S. 130A-88;  
Eff. October 1, 1985;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

#### **10A NCAC 42B .0105 MICROBIOLOGY**

- (a) This laboratory isolates and identifies anaerobic organisms and serves as a reference laboratory for confirmation of further identification of anaerobic bacteria.
- (b) The laboratory examines fecal specimens for enteric pathogens from symptomatic patients, typhoid carriers, and contacts of such individuals. Environmental samples, such as food and water from aquariums or turtle bowls are examined if they are implicated as vehicles of infection. This laboratory is the designated serotyping center for the state of all isolates of salmonella and shigella for confirmation and surveillance purposes.
- (c) This laboratory isolates and identifies pathogenic fungi from body tissues and fluids and serves as a reference laboratory for confirmation or further identification of fungi.
- (d) This laboratory examines fecal and other specimens from symptomatic patients for the eggs, cysts, and larvae of the intestinal parasitic worms and protozoa. Blood smears are examined for parasitic blood diseases, such as malaria. Reference specimens or prepared stained slides from preserved material, biopsy material and tissue aspirates for tissue parasites are also accepted. Identification of arthropods is made.
- (e) This laboratory accepts a wide variety of bacteria which have been isolated by hospital or other laboratories, which are unusual, difficult to identify, fastidious, or infrequently encountered, thereby serving as a reference laboratory for other laboratories.
- (f) Sputa and specimens from other sources are examined for mycobacteria, including MYCOBACTERIUM TUBERCULOSIS and all isolates are tested for drug susceptibility using the drugs most commonly used for treating tuberculosis.
- (g) This laboratory may examine, upon request of an authorized sender of specimens, a variety of other specimens as the public health may require.

*History Note:* Authority G.S. 130A-88;  
Eff. October 1, 1985;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, 2017.

#### **10A NCAC 42B .0106 VIROLOGY/SEROLOGY**

- (a) The services available for the laboratory diagnosis of viral infections are based on the following general approaches:
  - (1) the examination of serum for the demonstration of a significant increase in antibody titer to a given virus;
  - (2) the examination of pathological fluids, tissue, and other suitable material for the isolation and identification of the viral agent; and
  - (3) the examination of infected tissue to demonstrate the presence of viral material or for changes which are characteristic of a particular viral disease.
- (b) Several types of serological procedures and variations of those are used to study and detect evidence of rickettsial, bacterial, fungal and parasitic diseases as well as viruses.
- (c) Only the head of animals larger than the common gray squirrel shall be accepted. Gray squirrels and small animals, including bats, shall, when possible, be submitted intact.

*History Note:* Authority G.S. 130A-88;  
Eff. October 1, 1985;  
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 42B .0107 NEWBORN SCREENING FOR POMPE DISEASE, MPS-1, AND X-ALD**

Pompe disease, Mucopolysaccharidosis Type I (MPS I), and X-Linked Adrenoleukodystrophy (X-ALD) are added to the Newborn Screening Program. The process to develop and implement new tests for these conditions shall begin after the fee is established and adequate funds exist to acquire instrumentation, equipment, Program supplies,

Program personnel, perform assay validations, implement preventative follow-up interventions, secure necessary infrastructure, and with the assurance that the laboratory has met all federal, State, and local requirements.

*History Note:* Authority G.S. 130A-125;  
Eff. September 1, 2018.

**10A NCAC 42B .0108 FEES**

(a) The State Laboratory of Public Health shall charge a fee of one hundred thirty-two dollars (\$132.00) to cover the programmatic costs of the newborn screening performed by the State Laboratory of Public Health under 10A NCAC 42B .0102(a).

(b) In accordance with G.S. 130A-125, the Commission for Public Health, in consultation with the Secretary of the North Carolina Department of Health and Human Services, has determined that the fee listed in Paragraph (a) of this Rule is necessary to offset the cost of incorporating the conditions identified in 10A NCAC 42B .0102(a) in the Newborn Screening Program.

*History Note:* Authority G.S. 130A-125;  
Eff. January 1, 2021.