

1 10A NCAC 42B .0102 is proposed for amendment as follows:

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3 **10A NCAC 42B .0102 ~~CLINICAL CHEMISTRY/NEWBORN~~ NEWBORN SCREENING**

4 (a) This laboratory will ~~conduct screening for~~ examine specimens for evidence of certain inborn errors of metabolism,
5 for the detection of chronic diseases, diabetes, renal diseases, hypertension, certain clinical chemistry and hematology
6 tests when requested by authorized senders of specimens within the guidelines of the Division of Maternal and Child
7 Health and the Division of Public Health. the core conditions listed on the Recommended Uniform Screening Panel
8 developed by the Secretary of the United States Department of Health and Human Services and the Advisory
9 Committee on Heritable Disorders of Newborns and Children (the "RUSP"), which is hereby incorporated by
10 reference, including any subsequent editions and amendments, and available free of charge at
11 <https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html>. Specimens shall be submitted to this
12 laboratory for screening in accordance with the procedures set forth in 10A NCAC 43H .0314.

13 (b) ~~This laboratory performs tests for hemoglobinopathies such as sickle cell trait and disease. The process to develop~~
14 and implement new screening for the conditions described in Paragraph (a) of this Rule shall begin after the
15 screening fee is established and adequate funds exist to acquire instrumentation, equipment, Program supplies,
16 Program personnel, perform assay validations, implement preventative follow-up interventions, secure necessary
17 infrastructure, and with the assurance that the laboratory has met all federal, State, and local requirements.

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19 *History Note: Authority G.S. 130A-88; 130A-125;*

20 *Eff. October 1, 1985;*

21 *Amended Eff. September 1, 1990;*

22 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December*
23 *23, 2017.*