

1 10A NCAC 42B .0102 is amended with changes as published in 34:23 NCR 2176–2177 as follows:

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

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

15 (1) the screening fee set out in Rule .0108 of this Section is adjusted, as permitted by G.S. 130A-125(c);
16 [established and adequate]

17 (2) funds exist to acquire instrumentation, equipment, Program supplies, and Program [personnel,]
18 personnel; and

19 (3) the Program [perform] performs assay validations, [implement] implements preventative follow-
20 up interventions, [secure] secures necessary infrastructure, and [with the assurance that the
21 laboratory has met] meets all federal, State, and local requirements.

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

24 *Eff. October 1, 1985;*

25 *Amended Eff. September 1, 1990;*

26 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December*
27 *23, 2017; ~~2017~~.*

28 *Amended Eff. January 1, 2021.*