

1 10A NCAC 13S .0325 is proposed for adoption under permanent procedures as follows:
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3 **10A NCAC 13S .0325 LABORATORY SERVICES**

4 (a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure
5 to be performed, and will perform laboratory tests appropriate to their Clinical Laboratory Improvement Amendments
6 (CLIA) certification.

7 (b) The governing authority shall establish written policies regarding which surgical specimens require examination
8 by a pathologist.

9 (c) Each patient shall have laboratory testing as determined to be clinically necessary by the physician, or as required
10 by law. A record of the results of any tests performed will be included in the patient's medical record.

11 (d) The clinic shall maintain a manual in a location accessible by employees, that meets requirements for the level of
12 clinic's CLIA certification. This includes the procedures, instructions, and manufacturer's instructions for each test
13 procedure performed including:

14 (1) sources of reagents, and quality control procedures; and

15 (2) information concerning the basis for the listed "normal" ranges.

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17 History Note: Authority G.S. 131E-153; 131E-153.5; 143B-165.

18 Codifier determined that findings of need did not meet criteria for emergency rule on October 30,
19 2023;

20 Emergency Rule Eff. November 14, 2023;

21 Temporary Adoption Eff. February 8, 2024;

22 Adopted Eff. October 1, 2024.
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