

10A NCAC 13S .0325 LABORATORY SERVICES

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

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

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

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

- (1) sources of reagents, and quality control procedures; and
- (2) information concerning the basis for the listed "normal" ranges.

*History Note: Authority G.S. 131E-153.5; 143B-165;
Codifier determined that findings of need did not meet criteria for emergency rule on October 30, 2023;
Emergency Rule Eff. November 14, 2023;
Temporary Adoption Eff. February 8, 2024;
Eff. October 1, 2024.*