

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0645798	(X3) Date Survey Completed 01/19/2021
Name of Provider or Supplier Etowah Pathology Associates, Llc	Street Address, City, State 833 Campbell Hill Street, Suite 111, Marietta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 19, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Tissue-Tek E150 - E300 operator's guide and staff interview, the laboratory failed to record the Room Temperature (RT) and Relative Humidity (RH) as required by the manufacturer. Findings include: 1. Review of the Tissue-Tek E150 - E300 operator's guide revealed the RT is to be monitored and maintained between 10-40°C and the RH is to be monitored and maintained between 30-85%. 2. Interview with the lab director on 1/19/21 in the back right records room at 3:10 PM confirmed the RT and RH were not monitored.</p>