

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2020576	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Galen East Laboratory	Street Address, City, State 1651 Gunbarrel Rd, Suite 102-A, Chattanooga, TN	
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
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 observation of the laboratory, review of the manufacturer's operating manuals, environmental records request, and interview with the lead histotech, the laboratory failed to monitor room humidity for the Leica EG 1150 H Paraffin Embedding Station, Leica EG 1150 C Cold Plate, and Sakura Tissue-Tek SCA Coverslipper in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on April 13, 2023 at 9:30 a.m. revealed the Leica EG 1150 H Paraffin Embedding Station (serial #038837689), Leica EG 1150 C Cold Plate (serial #038838038), and Sakura Tissue-Tek SCA Coverslipper (serial #90060107) in use for processing tissues removed during surgical procedures in preparation for histopathology procedures. 2. Review of the manufacturer's operating manuals revealed the following: - Leica EG 1150 H Paraffin Embedding Station environmental conditions require a maximum relative humidity of 60%. - Leica EG 1150 C Cold Plate environmental conditions require a maximum relative humidity of 80%. - Sakura Tissue-Tek SCA Coverslipper environmental conditions require an operating humidity range 30% - 70%. 3. Request of environmental records revealed no records for monitoring room humidity available for surveyor review. 4. Interview on April 13, 2023, at approximately 11:45 a.m. with the lead histotech confirmed the laboratory failed to monitor room humidity for the use of the Leica EG 1150 H Paraffin</p>

Embedding Station, Leica EG 1150 C Cold Plate, and Sakura Tissue-Tek SCA Coverslipper in 2021, 2022, and 2023.