Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1094125	(X3) Date Survey Completed 11/06/2025
Name of Provider or Supplier Gut Pathology Llc	Street Address, City, State 480 Honeysuckle Road, Dothan, AL	

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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the Sakura Tissue Tek DRS Autostainer manual, the humidity logs in the Pathology lab, the patient logs and an interview with the Laboratory Director (LD) and the General Supervisor (GS), the laboratory failed to ensure environmental parameters specified on the log aligned with the manufacturer's operational requirements in the room where the Sakura Tissue Tek DRS Autostainer was utilized for patient testing. The surveyor noted the humidity recorded were below the manufacturer's established limits of 30-85 percent for 40 days out of the 61 days reviewed in March 2024 and April 2025. The findings include: 1. A review of the Sakura Tissue Tek DRS Autostainer manual revealed on page 13 the operational humidity requirements of 30-85 percent. However, the laboratory's humidity logs specified an acceptable humidity range of 20-60 percent. 2. Due to an inaccurate acceptable range on the log, the Sakura Tissue Tek DRS Autostainer was utilized 18 days in March 2024 and 22 days in April 2025 when the humidity was below the manufacturer's required environmental specifications without documentation of corrective action. 3. The patient testing logs revealed 3762 patient samples were

	processed when the humidity was below the manufacturer's acceptable operational range. 4. The LD and the GS confirmed the above findings during the exit conference on 11-06-2025 at 1:30 PM.