

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1045272	(X3) Date Survey Completed 02/23/2026
Name of Provider or Supplier Gastroenterology Specialist Inc	Street Address, City, State 3355 Burns Rd Ste 306, Palm Beach Gardens, FL	
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	An announced CLIA recertification survey was conducted at Gastroenterology Specialists Inc on February 23, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to have a step-by-step procedure for the preparation of 75% Alcohol and 95% Alcohol used in the Vacuum Infiltration Processor (VIP) from 06/16/2023 to 02/23/2026. Findings: 1.</p>

During a tour of the laboratory on 02/23/2026 at 9:30 AM, no 70% Alcohol or 95% Alcohol were observed in the laboratory's nonflammable cabinets. 2. Review of the VIP E300 Tissue - Maintenance QC log showed the laboratory used 70% Alcohol and 95% Alcohol. 3. Review of the procedure manuals signed by the Laboratory Director on 07/14/2025 showed there was no process with a step-by-step procedure for the preparation of 70% Alcohol and 95% Alcohol. 4. On 02/23/2026 at 3:05 PM, the Histotechnologist stated there was no procedure on making the 70% Alcohol and 95% Alcohol in the procedure manual.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview, the laboratory failed to have a log documenting the preparation of the reagents used in the Vacuum Infiltration Processor (VIP) from 06/16/2023 to 02/23/2026. Findings Included: 1. During a tour of the laboratory on 02/23/2026 at 9:30 AM, no 70% Alcohol or 95% Alcohol was observed in the laboratory's flammable cabinets. 2. Review of the VIP E300 Tissue - Maintenance QC log showed the laboratory used 70% Alcohol and 95% Alcohol. 3. Review of quality control logs showed there was no log that showed the date the dilutions were made, the lot number and expiration of the 100% alcohol used to make the dilution, and the date of expiration for the dilution. 4. During an interview on 02/23 /2026 at 3:05 PM, the Histotechnologist stated there was no log documenting the preparation of the 70% Alcohol and 95% Alcohol.