

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0942902	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Gastroenterology Specialists Of	Street Address, City, State 1656 Medical Blvd Ste 301, Naples, 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 OF SOUTHWEST FLORIDA PA on August 19, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on observation, record review, and staff interviews, the laboratory failed to retain Quality Control documents and Patient test reports for Hematoxylin & Eosin, Immunochemical stains for Alcian Blue (AB)/Periodic Acid-Schiff (PAS) and DIFF-Quick slide staining in Histopathology from October 05, 2024, through January 18, 2026. Findings included: 1. Review of the Procedure For Laboratory Records & Reports signed by the Laboratory Director on January 19, 2026, stated under "Records & Report Retention for Lean Lab models -All slides and blocks sent to APS in North Little Rock, Arkansas will be kept for a minimum of two (2) years for blocks and ten (10) years for slides. -The patient requisition forms and medical records will be filed in sequence with the accessioning number. Slides and blocks will be held where the professional component is performed (Advanced Pathology Solutions, North Little Rock, AR). -Test reports retained or will be available to retrieve a copy of the original report (including final, preliminary, and corrected reports). -Proficiency Testing records, and all information regarding documentation for microscopic slide review will be done at the lab, Advance Pathology Solutions. -Laboratory Quality Assessments will be completed annually." 2. Evidence of slides, blocks, and final test

	reports for testing period of October 05, 2024, through January 18,2026 were requested but not provided by the laboratory. 3. Review of Quality Assessment records for testing period October 05, 2024, through January 18,2026 were requested but not provided by the laboratory. 4. Interview on 08/19/2024 at 1:35 PM the Laboratory Director confirmed that the laboratory did not have testing prior to January 19, 2026, and existing CLIA number was transferred from a previous "READ ONLY" laboratory. No further information was provided.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of Histopathology testing at least twice annually for the year 2025, since last survey period October 05, 2024, through January 18, 2026 reviewed. Findings included: 1. Personnel records reviewed revealed that in the Histopathology section there were three testing personnel TP-A (histology technician), TP-B (histology technician), and TP-C (Laboratory Director, also General Supervisor and Technical Supervisor), as per CMS 209 Form signed by LD on 08/05/2026. The laboratory did not provide records of personnel from October 05, 2024, through January 18,2026. 2. Review of Subpart I, 42 CFR Part 493.901 through 493.959 revealed that there was no approved proficiency testing programs for the interpretation of stained tissues. 3. Review of the Procedure For Laboratory Records & Reports signed by the Laboratory Director on January 19, 2026, stated under "Records & Report Retention for Lean Lab models - Proficiency Testing records, and all information regarding documentation for microscopic slide review will be done at the lab, Advance Pathology Solutions." There was no procedure for Proficiency Testing prior to January 19, 2026. 4. Peer review records were requested for Histopathology from October 05, 2024, through January 18,2026, but not provided. 5. Interview on 08/19/2024 at 1:35 PM the Laboratory Director confirmed that the laboratory did not have testing prior to open date January 19, 2026, there were no record of peer review for this CLIA number was transferred from a previous "READ ONLY" laboratory. No further information was provided.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interviews, the laboratory failed to document maintenance for the microscope, Quality Control Temperature for Room and Processor, Reagent stainer log used for Hematoxylin & Eosin, and Immunochemical stains for Alcian Blue (AB)/Periodic Acid-Schiff (PAS) and DIFF-Quick slide staining in Histopathology from October 05, 2024, through January

18,2026. Findings included: 1- Review of the JAN 2026 Temperature & Maintenance LOG" revealed there was no testing recorded prior to January 19, 2026. 2- Surveyor requested records for stain H&E QC, PAS QC, Q-Diff QC and microscope maintenance of equipment from October 05, 2024, through January 18,2026, but records were not provided. 3- Interview on 08/19/2024 at 1:35 PM the Laboratory Director confirmed that the laboratory did not have testing prior to open date January 19 2026, there were no record of daily QC stain, equipment and room temperature, or microscope maintenance on days of testing from October 05, 2024, through January 18, 2026.