

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1048255	(X3) Date Survey Completed 08/25/2025
Name of Provider or Supplier Advanced Gastroenterology And Surgery Associates	Street Address, City, State 26540 Ace Ave, Ste A, Leesburg, 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 Advanced Gastroenterology and Surgery Associates on August 25, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control documents, and interview, the laboratory failed to document quality control information including lot numbers, expiration dates, and open dates for all reagents used in the Leica XL Autostainer and the Tissue-Tek VIP from 08/3/2023 to 08/25/2025, and the laboratory failed to maintain log documenting preparation of the reagents used in the Leica XL Autostainer and the Tissue-Tek VIP from 05/10/2023 to 08/25/2025. Findings: 1. Review of the Leica XL Autostainer and Coverslipper Quality Control log showed the laboratory used the following reagent in their Autostainer: Xylene, 100% Alcohol, Periodic Acid, Alkane Blue, Schiffs Reagent, Hematoxylin, Acid Alcohol, Bluing Reagent, Diff Quick, and Eosin. 2. Review of the Tissue-Tek VIP Maintenance log showed the laboratory used the following reagent in their Tissue-Tek VIP: 10 % Formalin, 100% Alcohol, 80% Alcohol, 75% Alcohol, and Xylene. 3. Review of the Reagent Log showed the last date any reagent was recorded as received on the log was 08/02/2023. No other reagent logs were available for review. 4. Review of the quality control log revealed there were no logs documenting the preparation of the 75% Alcohol, 80% Alcohol,</p>

and 0.175 Acid Alcohol. 5. During an interview on 08/25/2025 at 12:10 PM, Testing Personnel A stated they did not have a log documenting the preparation of reagents and did not have a reagent log.