

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2256191	(X3) Date Survey Completed 04/17/2023
Name of Provider or Supplier Advanced Gastroenterology Affiliates Pa	Street Address, City, State 7448 Docs Grove Circle, Suite 200, Orlando, 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 initial certification survey was conducted on April 17, 2023. Advance Gastroenterology Affiliates PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of peer review records and interview, the laboratory failed to verify accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemistry (IHC) stains using peer review in 2022. Findings: Review of the GI (Gastrointestinal) Pathology Reports showed that the first day of testing was 4/26/2022. Review of the "Quality (QA) Assessment Evaluation showed the only peer review was done on 04/06/2023. The Laboratory Directory evaluated the H&E stains and the following special stains: Alcian Blue (AB - mucopolysaccharides and glycoproteins stain), PAS/AB (Periodic Acid Schiff, polysaccharides stain/mucopolysaccharides and glycoproteins stain), and Trichrome (connective tissues stain). The Laboratory Directory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD117 (Cluster of Differentiation 117, stem cell IHC stain), and H. pylori (Helicobacter pylori IHC stain). On 04/17/2023 at 1:22 PM, the Laboratory Director stated there was not peer review done in 2022.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must</p>

be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (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, review of the GI (Gastrointestinal) Pathology Reports, and interview, the laboratory failed to have negative control slides for Immunohistochemical (IHC) stains for two (#2, #3) of three (#1 - #3) patients' slides reviewed. Findings: The laboratory performed only the microscopic examination of the slides. Three of three patients' slides and pathology reports reviewed had IHC stained slides. The laboratory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), H. pylori (Helicobacter pylori IHC stain) and CD117 (Cluster of Differentiation 117, stem cell IHC stain). Observation of the patient slides on 04/17/2023 at 2:45PM showed there were no negative control slides for the IHC stains for Patient #2 and #3. Patient #2 had IHC stained slides for CD3 and H. pylori, and the results of the patients' IHC stained slides were reported on the pathology report. Patient #3 had IHC stained slides for H. pylori and the results of the patients' IHC stained slide were reported on the pathology report. On 04/17/2023 at 2:22 PM, the Laboratory Director stated she could not find the negative control slides for the for CD3 and H. pylori for patient #2, and confirmed with the laboratory who performed the technical component (staining of the slides) that they had not stained the negative control slides. On 04/17/2023 at 2:51 PM, the Laboratory Director stated she could not find a negative control slide for H. Pylori for patient #3, and confirmed with the laboratory who performed the technical component that they had not stained a negative control slide.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the GI (Gastrointestinal) Pathology Reports and interview, the laboratory failed to have the correct name of the laboratory where the professional interpretation was performed for three of three patients, (#1, #2, #3). Findings: Review of the pathology reports for patient #1, #2 and #3 showed the name where "The professional interpretation was performed" was not the name of the laboratory. On 04/17/2023 at 2:59 PM, the Laboratory Director stated the name was wrong.