

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2257356	(X3) Date Survey Completed 08/09/2025
Name of Provider or Supplier Advanced Gastroenterology Associates, Pa	Street Address, City, State 902 Preskitt Rd Suite 300, Decatur, TX	
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of laboratory's standard operating procedures and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for five of five stains used in histopathology interpretations. Findings included: 1. Review of laboratory's standard operating procedure manual revealed the procedure failed to define the staining characteristics for intended reactivity for the following stains used by the laboratory for histopathology interpretations: Hematoxylin & Eosin (H&E) Alcian Blue/Periodic Acid Schiff (AB/PAS) Trichrome Helicobacter Pylori (H. Pylori) CD3 2. During an interview on 08/09/2025 at 11:09 a.m., the Laboratory Director, after review of records, confirmed the above findings. II. Based on review of laboratory policy, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to test and document Hematoxylin & Eosin (H&E), Alcian Blue/Periodic Acid Schiff (AB/PAS), and Trichrome stains intended reactivity to ensure predictable staining characteristics each day of use for six of six days in 2025 (random review July through August). Findings included: 1. Review of laboratory's standard operating procedure manual revealed the procedure failed to define the staining characteristics for intended reactivity for the following stains used by the laboratory for histopathology interpretations: Hematoxylin & Eosin (H&E) Alcian Blue/Periodic Acid Schiff (AB/PAS) Trichrome Refer to D5473, I. 2. Random</p>

review of daily slide quality control records revealed the laboratory failed to test and document the intended reactivity H&E, AB/PAS, and Trichrome stains on the following dates patients were tested and reported in 2025: 07/17/2025 Patient Accession #: 3354391-2025; stain: H&E 3354390-2025; stain: H&E 07/21/2025 Patient Accession #: 3354392-2025; stain: H&E, Trichrome 07/23/2025 Patient Accession #: 3355689-2025; stain: H&E, Trichrome 07/25/2025 Patient Accession #: 3356294-2025; stain: H&E, Trichrome 3356284-2025; stain: H&E, AB/PAS 3356283-2025; stain: H&E 3356307-2025; stain: H&E, Trichrome 3356304-2025; stain: H&E, AB/PAS 3356299-2025; stain: H&E 08/02/2025 Patient Accession #: 3358545-2025; stain: H&E 3358546-2025; stain: H&E 3358549-2025; stain: H&E 3358553-2025; stain: H&E 3358597-2025; stain: H&E 3358598-2025; stain: H&E 08/03/2025 Patient Accession #: 3358550-2025; stain: H&E 3358562-2025; stain: H&E, AB/PAS 3358520-2025; stain: H&E, AB/PAS 3358550-2025; stain: H&E 3358552-2025; stain: H&E; AB/PAS 3358600-2025; stain: H&E; AB/PAS 3358601-2025; stain: H&E; AB/PAS The laboratory failed to document H&E, AB/PAS, and Trichrome stains intended reactivity to ensure predictable staining characteristics. 3. During an interview on 08/09/2025 at 11:09 a.m., the Laboratory Director, after review of records, confirmed the above findings.

D5601

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

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must 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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to test and document Helicobacter Pylori (H. Pylori) and CD3 stains for positive or negative reactivity to ensure stain quality each day of use for four of four days in 2025 (random review July through August). Findings included: 1. Review of laboratory's standard operating procedure manual revealed the procedure failed to define the staining characteristics for intended reactivity for the following stains used by the laboratory for histopathology interpretations: H. Pylori CD3 Refer to D5473, I. 2. Random review of daily slide quality control records revealed the laboratory failed to test and document the H. Pylori and CD3 stains for positive or negative reactivity to ensure stain quality on the following dates patients were tested and reported in 2025: 07/21/2025 Patient Accession #: 3354392-2025; stain: CD3 07/23/2025 Patient Accession #: 3355689-2025; stain: CD3 07/25/2025 Patient Accession #: 3356294-2025; stain: CD3 3356284-2025; stain: H. Pylori 3356307-2025; stain: CD3 3356304-2025; stain: H. Pylori 08/03/2025 Patient Accession #: 3358562-2025; stain: H. Pylori 3358520-2025; stain: H. Pylori 3358552-2025; stain: H. Pylori 3358600-2025; stain: H. Pylori 3358601-2025; stain: H. Pylori The laboratory failed to document H. Pylori and CD3 stains for positive or negative reactivity to ensure stain quality. 3. During an interview on 08/09/2025 at 11:09 a.m., the Laboratory Director, after review of records, confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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 patient records and confirmed in interview, the laboratory failed to include the testing facility address on the final reports for 23 of 23 patients in 2025 (random review July-August). Findings included: 1. Review of patient records from 2025 (random sampling) revealed the following 23 final reports which did not include the testing facility address: 07/17/2025 Patient Accession #: 3354391-2025, 3354390-2025 07/21/2025 Patient Accession #: 3354392-2025 07/23/2025 Patient Accession #: 3355689-2025 07/25/2025 Patient Accession #: 3356294-2025, 3356284-2025, 3356283-2025, 3356307-2025, 3356304-2025, 3356299-2025 08/02/2025 Patient Accession #: 3358545-2025, 3358546-2025, 3358549-2025, 3358553-2025, 3358597-2025, 3358598-2025 08/03/2025 Patient Accession #: 3358550-2025, 3358562-2025, 3358520-2025, 3358550-2025, 3358552-2025, 3358600-2025, 3358601-2025 2. During an interview on 08/09/2025 at 11:09 a.m., the Laboratory Director, after review of records, confirmed the laboratory failed to include the testing facility address on the final reports for 23 of 23 patients in 2025.