| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>45D2257356 | (X3) Date Survey Completed<br>03/29/2023 |
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| **Name of Provider or Supplier**<br>Advanced Gastroenterology Associates, Pa | **Street Address, City, State**<br>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 |
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| **D0000** | The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, proficiency testing (PT)records, and confirmed in interview, the laboratory failed to have documentation of performing 1 of 1 semi-annual accuracy assessments for histopathology slide interpretations in 2022. Findings included: 1. Review of the CMS-116 form submitted on the day of the survey by the laboratory revealed the laboratory performed histopathology slide interpretations. 2. Review of PT records for 2022 revealed NO semi-annual accuracy assessments for histopathology slide interpretations. The laboratory was asked to provide semi-annual accuracy assessments for 2022. None were provided. The laboratory failed to have documentation of performing semi-annual accuracy assessments for histopathology slide interpretations in 2022. 3. During an interview on 03/29/2023 at 11:47 am, the Laboratory Owner confirmed the above findings. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies and confirmed in staff interview, it was revealed that 5 of 5 laboratory policies were not approved, signed, or dated by the laboratory director before use in 2022. Findings included: 1. Review of the laboratory's policy manual titled "DIAGNOSTIC SERVICE OF ANATOMIC PATHOLOGY" revealed the following policies: "STANDARD OPERATING PROCEDURE AND MANUAL HANDLING OF MICROSCOPIC SLIDES AND PATHOLOGIC REPORTS FOR Advanced Gastroenterology Associates, PA QUALITY CONTROL AND QUALITY ASSURANCE IN SURGICAL PATHOLOGY SERVICES ANATOMIC PATHOLOGY TURN-AROUND TIMES HISTOLOGY SLIDE DELIVERY AND QUALITY RECORD" The laboratory's policies were not approved, signed, or dated by the laboratory director before they began patient testing in 2022. 2. During an interview on 03/29/2023 at 11:47 am, the Laboratory Owner confirmed the above findings. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of laboratory policy 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 6 of 6 stains used in histopathology interpretations. Findings included: 1. Review of laboratory policy "QUALITY CONTROL AND QUALITY ASSURANCE IN SURGICAL PATHOLOGY SERVICES " revealed: "CRITERIA TO REQUEST IMMUNOSTAINS AND OTHER STUDIES - Pathology diagnosis should be established on morphology of routine H&E stained microscopic slide with consideration of cross pathology, patient's age and other clinical information as well as special studies if indicated by the following criteria: Confirm borderline or small focus of malignancy. Define distribution or extensiveness of tumor involvement for clinical staging. Cases with dysplasia or atypical changes suspicious for malignancy. Identify specific infectious organisms. Differentiate primary versus metastatic malignant neoplasms." 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 Cytomegalovirus (CMV) 2. During an interview on 03/29/2023 at 11:47 am, the Laboratory Owner 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 9 of 9 days in 2022 (random review July through October). Findings included: 1. Review of laboratory policy "HISTOLOGY SLIDE DELIVERY AND QUALITY RECORD" revealed: " Procedure: Pathology assistant should record the time at which the microscopic slides have been received from the commercial reference laboratory, and check for any damage or mislabeling of received slides. Pathologist should |

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| | examine the slides and record any deficiencies in tissue sectioning, levels and slide staining. Depending on the nature of the problem, the pathologist may elect to submit the problem slides to the histology laboratory or contact the lab supervisor to resolve the problem " 2. 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 2022: 07/21/2022 Patient IDs: 2355476- H&E, Trichrome 2355478- H&E, Trichrome 2355481- H&E 2355511- H&E, Trichrome 2355515- H&E, Trichrome THS22-35364- H&E THS22-35422- H&E, AB/PAS 07/27/2022 Patient IDs: THS22-36776- H&E, Trichrome 08/03/2022 Patient IDs: THS22-37936- Trichrome 08/12/2023 Patient IDs: THS22-39484- H&E 08/23/2022 Patient IDs: THS22-41762- H&E, AB/PAS THS22-41999- H&E, AB/PAS 09/09/2022 Patient IDs: THS22-44675- H&E 09/21/2022 Patient IDs: THS22-46279- AB/PAS THS22-46531- H&E, AB/PAS 09/27/2022 Patient IDs: THS22-47680- H&E 10/03/2022 Patient IDs: THS22-47869- Trichrome The laboratory failed to document H&E, AB/PAS, and Trichrome stains intended reactivity to ensure predictable staining characteristics. 3. During the exit interview at 12:30 pm, the Laboratory Owner, after review of records, confirmed the above findings. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(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. (f) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>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), CD3, Cytomegalovirus (CMV) stains for positive or negative reactivity to ensure stain quality each day of use for 6 of 6 days in 2022 (random review July through October). Findings included: 1. Review of laboratory policy "HISTOLOGY SLIDE DELIVERY AND QUALITY RECORD" revealed: " Procedure: Pathology assistant should record the time at which the microscopic slides have been received from the commercial reference laboratory, and check for any damage or mislabeling of received slides. Pathologist should examine the slides and record any deficiencies in tissue sectioning, levels and slide staining. Depending on the nature of the problem, the pathologist may elect to submit the problem slides to the histology laboratory or contact the lab supervisor to resolve the problem " 2. Review of daily slide quality control records revealed the laboratory failed to test and document the H. Pylori, CD3, CMV stains for positive or negative reactivity to ensure stain quality on the following dates patients were tested and reported in 2022: 07/21/2022 Patient IDs: 2355476- CD3 2355478- CD3 2355511- CD3 2355515- CD3 THS22-35422- H. Pylori, CD3 07/27/2022 Patient IDs: THS22-36776- CD3 08/03/2022 Patient IDs: THS22-37936- CD3, CMV 08/23/2022 Patient IDs: THS22-41762- CD3, H. Pylori THS22-41999- CD3, H. Pylori 09/21/2022 Patient IDs: THS22-46279- CD3, H. Pylori THS22-46531- CD3, H. Pylori 10/03/2022 Patient IDs: THS22-47869- CD3 The laboratory failed to document CD3, H. Pylori, and CMV stains for positive or negative reactivity to ensure stain quality. 3. During the exit |

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| | interview at 12:30 pm, the Laboratory Owner, after review of records, confirmed the above findings. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient records and confirmed in interview, the laboratory failed to include the testing facility address on the final reports for 5 of 20 patients in 2022 (random review July to October). Findings included: 1. Review of patient records from 2022 (random sampling) revealed the following 5 final reports which did not include the testing facility address: 07/21/2022 Chart #'s: 10716, 20989, 16966, 14183, 28743 2. During the exit interview at 12:30 pm, the Laboratory Owner, after review of records, confirmed the above findings. |