Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2008065	03/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Gastrointestinal Associates, Plc	20100 N 51st Ave Ste 615, Glendale, AZ	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the laboratory director (LD), the laboratory failed to establish test procedure for performing and reporting Immunohistochemical (IHC) stain results on patient specimens. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. The laboratory performs the IHC stains, CD3 and Helicobacter pylori (H. Pylori), on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. The laboratory failed to create a test procedure

	for each IHC stain listed above, including but not limited to, specimen labeling and identification, specimen processing, step-by step performance of the IHC stain process, control procedures, and a system for reporting patient results. 4. The LD interviewed on 3/14/24 at 2:40 PM confirmed the laboratory failed to establish a test procedure for performing and reporting IHC stain results on patient specimens for each IHC stain listed above.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on lack of written quality control procedures for Immunohistochemical (IHC) stains and interview with the laboratory director (LD), the laboratory failed to determine the control procedures for IHC stains based upon the performance specifications verified by the laboratory. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. The laboratory performs the IHC stains, CD3 and Helicobacter pylori (H. Pylori), on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. It is the practice of the laboratory to use previously tested patient specimens as positive and negative tissue controls for the IHC stains listed above. Reading of the control specimens is performed simultaneously with the patient slide. 4. No documentation was presented for review during the survey to indicate the laboratory determined the IHC control procedures for both positive and negative controls based upon the performance specifications verified by the laboratory for each IHC stain. The control procedures must include the frequency, type and number of control materials used for each IHC stain. 5. The LD interviewed on 3/14/2024 at 2:40 PM confirmed the laboratory failed to determine control procedures for the IHC stains as indicated above. 6. The number of patient specimens tested with IHC stains could not be determined at the time of the survey.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of positive and negative Quality Control (QC) documentation for Immunohistochemical (IHC) stains from 2022 through the date of the survey on 3/14/2024 and interview with the laboratory director (LD), the laboratory failed to check immunohistochemical stains for positive and negative reactivity each time of use. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. The laboratory performs the IHC stains, CD3 and Helicobacter pylori (H.

	Pylori), on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. No documentation of positive and negative stain acceptability for each IHC stain listed above was presented for review for testing that occurred during 2022, 2023, and 2024 (through the date of the survey conducted on 3/14/24). 4. The number of patient specimens tested with IHC stains during the timeframe indicated above could not be determined at the time of the survey. 5. The LD interviewed on 3/14 /2024 at 2:40 PM confirmed the laboratory failed to check each IHC stain for positive and negative reactivity each time of use during the timeframe indicated above.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for one out of one testing personnel and interview with the laboratory director (LD), the laboratory director failed to ensure that all testing personnel received the appropriate training and demonstrated that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for one out of one testing personnel who began grossing patients' specimens in May 2023, under the subspecialty of Histopathology. 2. The LD interviewed on 3/14/24 at 2:10 PM confirmed the laboratory failed to perform and document initial training for the testing personnel indicated above. 3. The laboratory's reported annual test volume for the subspecialty of Histopathology is 15,000.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the laboratory failed to provide evidence of academic credentials required to qualify one out of one testing personnel who performs the gross description of patients' specimens under the subspecialty of Histopathology. See D6171 for findings.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned

an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on lack of academic documentation presented for review for one out of one testing personnel who performs the gross examination on patient specimens and interview with the laboratory director (LD), one out one testing personnel failed to meet the required education qualifications to perform high complexity testing.

	Findings include: 1. The laboratory performs grossing and biopsy interpretations under the subspecialty of Histopathology, with a reported annual test volume of 15,000. 2. The CMS-209, Laboratory Personnel form submitted for review during the survey listed one testing personnel who performs the gross examination on patient specimens. 3. No evidence of acceptable academic credentials was presented for review during the survey to indicate one out of one testing personnel met the required education qualifications under 493.1489 in the CLIA regulations for Testing Personnel who perform high complexity testing. 4. The LD interviewed on 03/14/24 at 2:10 PM confirmed that the testing personnel stated above lacked the appropriate education documentation for the complexity of testing performed by the laboratory.