Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2044715	**(X3) Date Survey Completed** 02/11/2025
Name of Provider or Supplier Gastrointestinal Associates Of Texas, Pa	**Street Address, City, State** 17510 West Grand Parkway South, Suite 220, Sugar Land, 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	An unannounced complaint investigation was performed on February 3, 2025, for Intakes #TX00528091. The complaint was substantiated. The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory records, patient data, and staff interview, the laboratory director failed to ensure one of five testing personnel qualified to perform high complexity testing (grossing). Findings include: 1. The laboratory director failed to ensure one of five testing personnel qualified to perform high complexity testing (grossing). (Refer to D6102)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 a review of laboratory records, patient data, and staff interview, the laboratory director failed to ensure one of five testing personnel qualified to perform high complexity testing (grossing). Findings include: 1. A review of the laboratory's personnel records found that the laboratory director failed to ensure one of five testing personnel had the sufficient amount of education hours to perform high complexity testing (grossing). 2. A review of patient records found that the unqualified testing person performed grossing on twelve patient specimens on February 7, 2025. (See Patient Alias List: Patients 1-12) 3. In an interview on 2/10/2025 at 10:00 a.m. in the office, the Office Manager confirmed that each of the twelve patients on the patient list provided had specimens grossed in the laboratory on 02/07/2025 by the unqualified testing person.
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 a review of laboratory records, patient data, and staff interview, one of five testing personnel failed to qualify for high complexity testing (grossing). (Refer to D6171)
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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted

	occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on a review of laboratory records, patient data, and staff interview, one of five testing personnel failed to qualify for high complexity testing (grossing). Findings include: 1. A review of the laboratory's personnel records found one of five testing persons failed to meet the qualifications for high complexity testing (grossing). The laboratory provided a chemical engineering equivalence degree, but the degree plan failed to include the required number of biology hours. 2. A review of patient records found that the unqualified testing person performed grossing on twelve patient specimens on February 7, 2025. (See Patient Alias List: Patients 1-12) 3. In an interview on 2/10/2025 at 10:00 a.m. in the office, the Office Manager confirmed that each of the twelve patients on the patient list provided had specimens grossed in the laboratory on 02/07/2025 by the unqualified testing person.