Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161348	11/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Texas Gastroenterology Institute	110 E Savannah Ave, Building C, Suite 203, Mcallen, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient samples, and staff interview, the laboratory failed to have documentation of following its policy for specimen tracking for 22 of 22 samples from July 1, 2022 to July 6, 2022. The findings included: 1. A review of the laboratory's policy titled "Quality Control (QC) Program" approved by the laboratory director on March 21, 2022, under the section titled 'Case and Specimen Tracking' stated: (A1) All cases for histology will be accessioned. The following data is entered during accessioning: 1) Patient Name and Medical Records Number 2) Specimen Source 3) Date and time of specimen collection 4) Date and time of specimen receipt 5) Surgeon or Clinical collecting and submitting specimen 6) Pathologist assigned to evaluation case 2. A random sampling of patient records reviewed between July 1, 2022 to July 6, 2022 identified 22 of 22 samples missing documentation of the time of collection. They were: MARGON203 JUAORT009 SUEDUL000 ARMCHA002 OFESAE001 ROBRIC000 GUICER000

	DENJUA000 CONTAM000 SANTREO12 DANAND000 NINMOR001 DORGAR013 SYLHER002 ALBBAL000 6658576 MARHER177 ERNROD008 ROSMON004 ROSREY003 MARZUN014 SERALV000 3. An interview with the testing person (grossing) on 11/16/2022 at 1045 hours in the laboratory after his review of the records confirmed the findings.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In

	dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m). This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of patient records, and confirmed in interview, the laboratory failed to review within 24 hours of all physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for 22 of 22 samples from July 1, 2022 to July 5, 2022. The findings included: 1. A review of the laboratory's personnel records for testing personnel #1 (as listed on Form CMS 209) found no documentation of records to qualify him as a laboratory director or technical supervisor for high complexity testing in the specialty of histopathology. Therefore, grossing must be reviewed by the technical supervisor within 24 hours. 2. A random review of patient reports whose grossing was performed by testing personnel 1 from July 1, 2022 to July 5, 2022 found 22 of 22 grossed specimens did not document review of the grossing by the technical supervisor (TS) within 24 hours. Patient ID Date of Service MARGON203 07-01-2022 JUAORT009 07-01-2022 SUEDUL000 07-01-2022 ARMCHA002 07-01-2022 OFESAE001 07-01-2022 ROBRIC000 07-01-2022 GUICER000 07-01-2022 DENJUA000 07-05-2022 CONTAM000 07-05-2022 SANTREO12 07-05-2022 DANAND000 07-05-2022 NINMOR001 07-05-2022 DORGAR013 07-05-2022 SYLHER002 07-05-2022 ALBBAL000 07-05-2022 6658576 07-05-2022 MARHER177 07-05-2022 ERNROD008 07-05-2022 ROSMON004 07-05-2022 ROSREY003 07-05-2022 MARZUN014 07-05-2022 SERALV000 07-05-2022 3. An interview with the laboratory director on November 16, 2022 at 1015 hours in the conference room confirmed that there is no review of the grossing. Key: CMS - Centers for Medicare and Medicaid Services