Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161857	01/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Texas Institute Of Digestive Health, Pllc	1919 North Loop West, Ste 299, Houston, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to have documentation of performing accuracy assessments twice annually in 2020 for the grossing of histology specimens. Findings include: 1. The laboratory was asked to provide documentation of performing accuracy assessments twice annually in 2020 for the grossing of histology specimens. No documentation was provided. 2. An interview with the laboratory director on 1/20/21 at 10:20 a.m. in the nurse's station revealed the laboratory did not perform twice annual accuracy assessments for grossing in 2020. This confirmed the above findings.
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 a review of laboratory's procedure manual, a review of the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to have a written procedure for how it will ensure the accuracy, at least twice annually, for the grossing of histology specimens Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory failed to have a written procedure for how it will perform the twice annual accuracy assessments for the grossing of histology specimens. 2. An interview with the laboratory director on 1/20/21 at 10:30 a.m. in the nurse's station, confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, a review of the laboratory's policies, surveyor observation of reagents and control slides stored in the laboratory, a review of the laboratory's temperature logs, a random review of patient test records from December 2020, and staff interview, it was revealed that the laboratory failed to ensure the following reagents and control slides were stored at temperatures required by the manufacturer: a) StatLab Periodic Acid 1% Solution b) StatLab Helicobacter Control Slides c) StatLab Alcian Blue Control Slides Findings include: 1. A review of the manufacturer's instructions for the following reagents and control slides indicated the storage requirements: a) StatLab Periodic Acid 1% Solution "Store in a dry, cool

	and well-ventilated place." b) StatLab Helicobacter Control Slides "Storage: 15 - 30 C" c) StatLab Alcian Blue Control Slides "Storage: 15 - 30 C" 2. A review of the laboratory's policy titled 'Supply/Reagent Receipt and Storage' revealed the following: "All supplies are to be store according to manufacturer's recommended temperature." 3. Surveyor observation on 1/20/21 at 12:00 p.m. of the reagents and control slides stored in the laboratory revealed the following: a) 1 bottle of StatLab Periodic Acid 1% Solution (lot: 109698 exp. 5/31/22) stored in the laboratory refrigerator b) 2 boxes of StatLab Helicobacter Control Slides (1 box lot: 65477H exp. 2/1/22 and 1 box lot: 65757H exp. 5/1/22) stored in the laboratory refrigerator c) 2 boxes of StatLab Alcian Blue Control slides (1 box lot: 65267H exp. 2/1/22 and 1 box lot: 65937H exp. 5/1 /22) stored in the laboratory refrigerator 4. A review of the laboratory's Temperature Logs for the refrigerator lists the acceptable temperature range as 2- 4 C. 5. A random review of patient test records from December 2020 revealed the following 10 patient specimens were processed when the reagents and control slides were not stored according to the manufacturer's requirements: Patient Specimen ID: HT20-01107 Date: 12/16/20 Patient Specimen ID: HT20-01110 Date: 12/16/20 Patient Specimen ID: HT20-01129 Date: 12/22/20 Patient Specimen ID: HT20-01130 Date: 12/22/20 Patient Specimen ID: HT20-01131 Date: 12/22/20 Patient Specimen ID: HT20-01157 Date: 12/30/20 Patient Specimen ID: HT20-01159 Date: 12/30/20 Patient Specimen ID: HT20-01160 Date: 12/30/20 Patient Specimen ID: HT20-01168 Date: 12/30/20 Patient Specimen ID: HT20-01169 Date: 12/30/20 6. An interview with the laboratory director on 1/20/21 at 12:15 p.m. revealed the laboratory stored the reagents and control slides in the refrigerator because this was how they have always done it. This confirmed the above findings. Key: C = degrees Celsius
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the the laboratory's Temperature Logs for November 2020 to December 2020, a review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of performing corrective action for 10 of 61 days from November 2020 to December 2020 when the laboratory's room temperature readings were documented outside of the acceptable ranges. Findings include: 1. A review of the laboratory's Temperature Logs from November 2020 to December 2020 revealed the following 10 days where the laboratory's room temperature exceeded the acceptable ranges: Room Temperature 55 - 80F 11/3/20 84F 11/4/20 81F 11/11/20 82F 11/16/20 84F 11/17/20 81F 11/18/20 82F 11/20/20 82F 12 /10/20 83F 12/17/20 81F 12/22/20 82F 2. A review of patient test records revealed the following 8 patient specimens were processed when the room temperature was documented outside of the acceptable ranges: Patient Specimen ID: HT20-00937 Processed 11/4/20 Patient Specimen ID: HT20-00941 Processed 11/4/20 Patient Specimen ID: HT20-00987 Processed 11/17/20 Patient Specimen ID: HT20-00991 Processed 11/17/20 Patient Specimen ID: HT20-01076 Processed 12/10/20 Patient Specimen ID: HT20-01088 Processed 12/10/20 Patient Specimen ID: HT20-01129 Processed 12/22/20 Patient Specimen ID: HT20-01130 Processed 12/22/20 3. An

	interview with the laboratory director on 1/20/21 at 11:20 a.m. in the nurse's station, after review of the records, confirmed the above findings. Key: F - Degrees Fahrenheit
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed that the laboratory failed to have documentation of the technical supervisor performing competency assessments in 2020 on 2 of 3 testing personnel for high complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/13/21) revealed the laboratory identified 3 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed no documentation of the technical supervisor performing competency assessments in 2020 for the following 2 testing personnel for high complexity testing: Testing person # 1 Testing Person # 2 * Further review of the competency assessments for the above listed testing personnel revealed the competency assessments for 2020 were performed by someone who does not qualify to be a technical supervisor. 3. An interview with the laboratory director on 1/20/21 at 10:05 a.m. in the nurse's station, after review of the records, confirmed the above findings.
D6174	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Based on a review of the submitted CMS 209 form, a review of the laboratory's personnel records, a review of the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to ensure that 1 of 3 testing personnel performed tests authorized by the laboratory director. Findings include: 1. A review of the submitted CMS 209 form (signed by the laboratory director on 1/13/21) revealed the laboratory employed 3 testing personnel to perform high complexity testing. 2. A review of the laboratory's personnel records revealed no documentation of the laboratory director's authorization to test for testing person #2. 3. A review of the laboratory's testing records revealed the laboratory began testing on November 11, 2019 with an estimated annual test volume of 986. 4. An interview with the laboratory director on 1/20/21 at 9:30 a.m. in the nurse's station, after review of the records, confirmed the above findings.