

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2161857	(X3) Date Survey Completed 11/10/2022
Name of Provider or Supplier Texas Institute Of Digestive Health, Pllc	Street Address, City, State 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 was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D6143	<p>GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461</p> <p>(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</p>

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 a review of the laboratory's CMS 209 form, a random review of patient reports from 2021 and 2022, and staff interview, it was revealed that the laboratory failed to have documentation of the technical supervisor reviewing the gross examination of patient's specimens within 24 hours for 5 of 14 patient's reports reviewed in 2021 and 2022. Findings include: 1. A review of the laboratory's CMS 209 form revealed the laboratory listed testing person (TP) #1 as performing gross examinations of patient's specimens. TP#1 was qualified to perform the high complexity test under regulation 493.1489 but was not qualified as a technical supervisor (TS) under regulation 493.1449. 2. A random review of the laboratory's patient reports from 2021 and 2022 revealed the following 5 patient's specimens were grossed by TP#1 and the laboratory failed to have documentation of the technical supervisor reviewing the grossing within 24 hours: Patient: HT21-825 Grossed by TP#1 on 8/20/21 10:00 am Reviewed by TS on 8/23/21 *time was not documented Patient: HT21-826 Grossed by TP#1 on 8/20/21 10:00 am Reviewed by TS on 8/23/21 *time was not documented Patient: HT21-827 Grossed by TP#1 on 8/20/21 10:00 am Reviewed by TS on 8/23/21 *time was not documented Patient: HT21-828 Grossed by TP#1 on 8/20/21 10:00 am Reviewed by TS on 8/23/21 *time was not documented Patient: HT21-829 Grossed by TP#1 on 8/20/21 10:00 am Reviewed by TS on 8/23/21 *time was not documented 3. An interview with the laboratory director on 11/10/22 at 9:45 a.m. in the conference room, after review of the records, confirmed the above findings. .