Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2007716	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Central Texas Digestive Disease Association	**Street Address, City, State** 2206 E Villa Maria, Bryan, 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 entrance conference was held with the laboratory histotechnician. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory histotechnician at the exit conference. The laboratory histotechnician was 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.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Center for Medicare & Medicaid Services (CMS) 116 form, laboratory policy, manufacturer instructions, Daily Quality Control (QC) logs, patient requisitions and confirmed in staff interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for Hematoxylin & Eosin (H&E) for 6 of 6 patients reviewed

	in 2022. Findings Included: 1. Review of CMS-116 for submitted at time of survey revealed 8,300 histopathology tests performed in 2022. 2. Review of laboratory policy revealed all histopathology slides submitted for testing are stained with Hematoxylin and Eosin (H&E) stain upon arrival. The laboratory did not define predictable staining characteristics of the H&E stain. 3. Review of manufacturer's instructions for, "Thermo Scientific Hematoxylin and Eosin-Y Stain" revealed the following staining characteristics: "Thermo Scientific Bluing Reagent is used to enhance the color of the nuclei after hematoxylin staining. This is achieved by changing the nuclear chromatin stain from reddish-blue to a crisp purple blue." Further review revealed the following: "Thermo scientific Eosin-Y is an acidified, alcoholic counterstain that provides excellent delineation of cytoplasmic components in shades of red and pink." 4. Review of laboratory, "Daily QC Workload" revealed the following days H&E QC was performed prior to patient testing: a. 05/05/2022; 11/03/2022; 11/07/2022; 11/08 /2022; 11/29/2022 Staining characteristics were not defined on the workload. 5. Review of patient requisitions revealed the following patients stained with H&E stain in 2022, and predictable staining characteristics were not defined: May 2022 a. Patient Medical Record Number (MRN): M000361343 Grossing performed on: 05/05/2022 November 2022 a. Patient Medical Record Number (MRN): M000376464 Grossing performed on: 11/03/2022 b. Patient MRN: M000439157 Grossing performed on: 11 /07/2022 c. Patient MRN: M001098099 Grossing performed on: 11/08/2022 d. Patient MRN: M000391656 Grossing performed on: 11/08/2022 e. Patient MRN: M000642724 Grossing performed on: 11/29/2022 6. During an interview on 02/08 /2023 at 11:10 a.m. with TP-1 in the breakroom, TP-1 confirmed the above 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 Center for Medicare & Medicaid Services (CMS) 209 form submitted at time of survey, patient test requisitions, and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 1 of 5 patient specimens reviewed in May 2022 and 5 of 10 patient specimens reviewed in November 2022. Findings Included: 1. Review of the CMS 209 form listed the laboratory director as the clinical consultant, technical supervisor (TS), and general supervisor (GS). and testing person (TP). The form included one testing person (TP-1) who performed the gross examinations of specimens received in the laboratory. The laboratory director/ technical supervisor/ general supervisor was not onsite. TP-1 did not qualify as a technical supervisor or general supervisor, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions including measurement of the specimen. 2. Random review of patient test requisitions revealed the following gross examinations performed by TP-1, not reviewed by the general supervisor within 24 hours: May 2022 a. Patient Medical Record Number (MRN): M000361343 Grossing performed on: 05/05/2022 Reviewed by GS: 05/10/2022 Total days to review after grossing: 5 days November 2022 a. Patient Medical Record Number (MRN): M000376464 Grossing performed on: 11/03/2022 Reviewed by GS: 11/09/2022 Total days to review after grossing: 6 days b. Patient MRN: M000439157 Grossing performed on: 11/07/2022 Reviewed by GS: 11/09/2022 Total days to review after grossing: 2 days c. Patient MRN: M001098099 Grossing performed on: 11/08/2022 Reviewed by GS: 11/10/2022 Total days to review after grossing: 2 days d. Patient MRN: M000391656 Grossing performed on: 11/08/2022 Reviewed by GS: 11/10/2022 Total days to review after grossing: 2 days e. Patient MRN: M000642724 Grossing performed on: 11/29/2022 Reviewed by GS: 12/01/2022 Total days to review after grossing: 2 days The general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were

	reviewed within 24 hours for 1 of 5 patient specimens reviewed in May 2022 and 5 of 10 patient specimens reviewed in November 2022. 3. During an interview on 02/08 /2023 at 10:20 a.m. with TP-1 in the breakroom, TP-1 confirmed the above findings.