

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2103718	(X3) Date Survey Completed 10/10/2019
Name of Provider or Supplier Texas Heart Institute Cv Pathology Laboratory	Street Address, City, State 6770 Bertner Avenue Room O 511, 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	<p>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.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observations, review of the laboratory records, and confirmed in interview, the laboratory failed to document the reactivity for 3 of 3 stains used for the macroscopic examination of the electron microscopy test. Findings were: 1. A tour of the laboratory on 10/10/19 at 1020 hours revealed the following stains used in the laboratory. Basic Fuchsin - Lot No.: 050509 Methylene Blue - Lot No.: 160830 Azur Blue - Lot No.: 130225 2. Random review of the 2017-2019 patient records revealed no documentation of the reactivity of the above stain used for the macroscopic</p>

examination of the electron microscopy test. Patient Id EM17-073 EM18-100 EM18-139 EM19-005 EM16-067 EM19-001 EM19-024 S19-14136 S19-13440 EM19-102 EM19-100 3. An interview with the general supervisor on 10/9/19 at 1125 hours in the office confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records from 2017-2019, and confirmed in interview, the laboratory failed to include the name and address of laboratory location where the macroscopic examination of the electron microscopy test was performed. Findings were: 1. Random review of the laboratory final reports from 2017 - 2019 revealed no documentation of the name and address of the laboratory location where the macroscopic examination of the electron microscopy test was performed. Patient Id EM17-073 EM18-100 EM18-139 EM19-005 EM16-067 2. An interview with the general supervisor in the office on 10/10/19 at 1050 hours confirmed the above findings. She acknowledged that the final report should include the laboratory name and address.

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(l)(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 patient test reports and interview, the laboratory failed to review within 24 hours of all physical examinations/descriptions of tissue for the electron microscopy test. Finding were: 1. A random review of the patient reports from 2018 -2019 revealed 6 of 10 test reports which did not document review of the macroscopic examination of the electron microscopy test by the technical supervisor (TS) within 24 hours. Patient ID EM19-001, processed 1/4/19, reviewed 1/9/19, elapsed time 5 days Patient ID EM19-024, processed 3/20/19, reviewed 3/22/19, elapsed time 2 days Patient ID S19-14136, processed 10/1/19, reviewed 10/4/19, elapsed time 3 days Patient ID S19-13440, processed 9/17/19, reviewed 9/23/19, elapsed time 5 days Patient ID EM19-102, processed 9/27/19, reviewed 10/2/19, elapsed time 5 days Patient ID EM19-100, processed 9/24/19, reviewed 9/28/19, elapsed time 4 days 2. An interview with the general supervisor on 10/10/19 at 1120 hours in the office confirmed the above findings.