

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2293799	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier Texas Cardiology Associates Of Houston	Street Address, City, State 19502 Mckay Dr, Suite 203a, Humble, 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 announced validation survey of the laboratory was conducted on 09/11/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, method verification studies, test volumes and staff interview, the laboratory failed to document verification of its patient population's normal ranges prior to start of testing of patient samples for 3 of 3 test platforms performed by the laboratory, the Avoximeter Hemoglobin /Oxyhemoglobin, the i-Stat Chem 8, and the i-Stat ACT (activated clotting time). Findings included: 1. Review of laboratory's policy " Pre-Analytic Policies and Procedures" (effective date 11/01/2023) revealed: "The laboratory director's or Technical Consultant's signature on the completed documents (sic) that the Analyzer meets this laboratory's specifications for accuracy, precision, reference (normal) ranges, and reportable ranges." 2. Review of the laboratory's method verification studies for its 3 test platforms revealed the studies were performed and approved by laboratory director/technical consultant as follows: a. Avoximeter Hemoglobin /Oxyhemoglobin - completed/approved on 01/26/2024 b. i-Stat Chem 8 cartridge -</p>

completed/approved on 11/03/2023 c. i-Stat ACT cartridge - completed/approved on 11/03/2023 3. Further review of the above method verification studies revealed none of the 3 method verification studies had documented verification of normal ranges for laboratory's patient population prior to start of testing patient samples. 4. Review of laboratory's submitted test volumes for the above test platforms revealed the laboratory estimated an annual volume of 550 tests. 5. In an interview on 09/11/2024 at 1000 hours via an online conference call in the facility's nursing station, the laboratory's director (as indicated on submitted Form CMS 209) stated that the laboratory used manufacturer's normal ranges but did not complete verification of normal ranges for its own patient population. This confirmed the findings.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies/procedures, method verification studies, test volumes and staff interview, the laboratory director failed to ensure the laboratory documented verification of its patient population's normal ranges prior to start of testing of patient samples for 3 of 3 test platforms performed by the laboratory, the Avoximeter Hemoglobin/Oxyhemoglobin, the i-Stat Chem 8, and the i-Stat ACT (activated clotting time). Refer to D5421.