

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2149371	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Crockett Medical Center	Street Address, City, State 1100 East Loop 304, Crockett, 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 unannounced complaint investigation conducted March 6, 2023, and March 7, 2023, found the laboratory out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Complaint # TX00446480 was substantiated with deficiencies 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 surveyor observations, document review, and interview with the Laboratory Director, the laboratory failed to verify accuracy, precision, reportable range, and patient normal ranges prior to performing patient testing on two of two OPTI-CCA blood gas analyzers. The findings included: 1. Based on surveyor observations in the laboratory at 13:44 hours on 3/6/2022, the laboratory used two OPTI-CCA TS2 blood gas analyzers for patient testing. The two analyzers were serial numbers OP6-005431 and OP6-001374. 2. Based on review of documentation, the laboratory began using the analyzers in the laboratory in June of 2022, nine months prior to the date of the investigation. 3. In an interview at 15:39 hours on 3/6/2023 via telephone, the Laboratory Director stated he noticed the analyzers did not have verification studies performed prior to patient use and had initiated the purchase of a new blood gas analyzer from a different manufacturer.</p>

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of laboratory personnel files, the Centers for Medicare and Medicaid (CMS) personnel form 209, and confirmed in an interview, the laboratory director failed to ensure that three of seven personnel had the appropriate documentation of training before testing patients' specimens. The findings include: 1. Review of laboratory personnel files included three travel testing persons (TP), listed on the CMS209, and their start dates: TP 3 - Start date of 12/20/2022 TP 4 - Start date of 1/16/2023 TP 5 - Start date of 1/26/2023 2. In an interview on 3/7/2023 at 10:25 hours, in the laboratory, the laboratory director confirmed that the documentation of training had not been performed before patient testing had occurred.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of laboratory personnel files, the Centers for Medicare and Medicaid (CMS) personnel form 209, and confirmed in an interview, the laboratory failed to ensure that one of seven testing personnel met the qualification requirements of 493.1423 to perform moderate complexity testing. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official 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); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of laboratory personnel files, the Centers for Medicare and Medicaid (CMS) personnel form 209, and confirmed in an interview, the laboratory failed to ensure that one of seven testing personnel had the educational documentation to meet the qualifications for moderate complexity testing personnel outlined at 493.1423 (b). The findings include: 1. Review of laboratory personnel files did not include diplomas, degrees, or transcripts, that could be used for qualifying as a testing person, for testing person (TP) 3. Surveyor queried for TP 3's educational records on 3/6/2023 at 1520 hours. Email correspondence was provided on 3/7/2023 at 11:26 hours from the travel tech placement company stating TP 3 had 'no diploma on file'. No other documentation was provided. 2. In an interview on 3/7/2023 at 11:30 hours, in the laboratory, the laboratory director confirmed that the laboratory had not ensured that the educational documentation needed to qualify TP 3 as a moderate complexity testing person.