

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2149371	(X3) Date Survey Completed 08/22/2023
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 was conducted on 8/22/2023. The laboratory was in compliance with the Requirements for Laboratories found at 42 CFR part 493. Complaint TX00436561 was substantiated with standard deficiencies cited.
D5555	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)</p> <p>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory temperature records, and confirmed in an interview, the laboratory failed to ensure the appropriate documentation of temperatures for the storage of blood products for transfusion for 10 of 36 weeks reviewed from December 2022 to August 2023. The findings included: 1. A review of the laboratory policy titled "Blood Bank Refrigerator Check" had the following instructions for the continuous temperature monitoring recording charts: "Blood bank recording charts shall be changed weekly." 2. Review of the laboratory blood bank continuous monitoring recording charts, from December 7, 2022, to August 16, 2023, had the following 10 instances where the temperature recording elapsed the weekly (7 days) change requirement causing the elapsed temperature recording to overlay previous temperature recordings: December 2022: Start: 12/7/2022 at 12:45 - End 12/16/2022 at 07:14 10 days from the start date to the end date, end date included. Start: 12/16/2022 at 07:14 - End 12/25/2022 at 15:10 9 days from the start date to the end date, end date included. Start: 12/25/2022 at 15:10 - End: 1/4/2023 at 07:30 10 days from the start date to the end date, end date included. January</p>

2023: Start: 1/11/2023 at 07:01 - End: 1/18/2023 at 08:50 8 days from the start date to the end date, end date included. Start: 1/18/2023 at 08:50 - End: 1/25/2023 at 17:50 8 days from the start date to the end date, end date included. February 2023: Start: 2/22/2023 at 11:10 - End: 3/1/2023 at 16:50 8 days from the start date to the end date, end date included. March 2023: Start: 3/8/2023 at 18:00 - End 3/17/2023 at 09:05 10 days from the start date to the end date, end date included. Start: 3/22/2023 at 08:30 - End 3/30/2023 at 07:50 9 days from the start date to the end date, end date included. April 2023: Start: 4/12/2023 at 07:25 - End 4/19/2023 at 13:00 8 days from the start date to the end date, end date included. May 2023: Start: 5/31/2023 at 08:00 - End 6/15/2023 at 1200 16 days from the start date to the end date, end date included. 3. In an interview on 8/22/2023 at 11:30 hours, in the laboratory, testing personnel (TP) 1 confirmed that the continuous temperature monitoring chart system had elapsed the weekly (7 day) change requirement.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policy, laboratory document, laboratory temperature charts, and confirmed in interview, the laboratory failed to have a mechanism in place for the identification and correction of issues with the continuous monitoring system for three of seven days reviewed from 8/9/2023 to 8/16/2023. The findings included:
1. Review of the laboratory policy titled "Blood Storage Policy" had the following statements: "Per AABB Standards Packed Red Blood Cells (PRBC's) must be stored between 1 and 6 (degrees) C (Celsius) This refrigerator is monitored 24 hours a day by a temperature graph recorder and is checked every morning as well during daily maintenance procedures." 2. Review of the laboratory continuous monitoring chart system had the following three days where the graph was recording a temperature of 0 (degrees) C: Wednesday 8/9/2023 at 12:29 hours to Saturday 8/13/2023 at approximately 4:00 hours. A review of the August 2023 form titled "Blood Bank Temp Log" had the following daily temperature documentation recorded by testing personnel for the chart system on days where the chart was recording 0 (degrees) C : 8/9/2023 - 4 (degrees) C 8/10/2023 - 4 (degrees) C 8/11/2023 - 4 (degrees) C 8/12/2023 - 4 (degrees) C 8/13/2023 - *recal 4 (degrees) C 3. In an interview on 3/22/2023 at 11:25 hours, in the laboratory, testing personnel (TP) 1 confirmed the discrepancy in the temperature recorded versus the temperature documented, and that the testing personnel had not documented the chart temperature appropriately.