

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659838	(X3) Date Survey Completed 07/10/2024
Name of Provider or Supplier Throckmorton County Memorial Hospital	Street Address, City, State 802 North Minter Avenue Box 729, Throckmorton, 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 onsite recertification survey conducted July 10, 2024, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry analyzer verification studies, calibration verification records, and interview with facility personnel, the laboratory failed to perform</p>

calibration verification studies at least every six months for three of three analytes reviewed between May 2023 and July 2024. The findings included: 1. Based on review of chemistry analyzer verification studies, the laboratory verified and put into use a Siemens EXL Dimension chemistry analyzer in May of 2023. 2. Based on review of the sodium, potassium, and chloride instructions for use, the analyzer calibrates these analytes every two hours with two standards. 3. In an interview at 14:09 hours on 7/10/2024, the laboratory director confirmed the laboratory had not yet performed calibration verification studies for sodium, potassium, and chloride analytes.

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:

Based on review of laboratory policy, laboratory continuous monitoring charts, and confirmed in interview, the laboratory failed to have a mechanism in place to ensure the continuously monitoring chart recorder was accurately recording the temperature of the refrigerator, used for the storage of transfusion services blood products, for 201 of 560 days reviewed from December 26, 2022 to July 8, 2024. The findings included: 1. In a tour of the laboratory on 7/10/2024 the surveyor observed a Thermo Scientific Jewett refrigerator, with a continuous monitoring chart recorder on the floor of the laboratory, used for the storage of transfusion services blood products. 2. Review of the laboratory policy titled "Standard Operating Procedure, General Blood Bank Policy", section "O Negative Unit Storage InHouse and Transport" had the following information: "1. Throckmorton County Memorial Hospital keeps 2 units of O negative PRBC in storage and available for Emergency release. 2. Storage temperature for all whole blood units is 1-6C." 3. Review of the continuous monitoring wheel charts from December 26, 2022 to July 8, 2024 included the following 201 days where the recorded temperature was out of the 1-6 (degree) C range: Date Range - Recorded temperature - days temperature out 12/26/2022 to 01/02/2023, 0 (degrees) C, 7 days 01/24/2023 to 01/27/2023, 0 (degrees) C, 4 days 01/30/2023 to 02/06/2023, 0 (degrees) C, 7 days 02/13/2023 to 02/20/2023, 0 (degrees) C, 7 days 02/27/2023 to 03/06/2023, 0 (degrees) C, 7 days 03/06/2023 to 03/13/2023, 0 (degrees) C, 7 days 03/15/2023 to 03/17/2023, 0 (degrees) C, 2 days 03/20/2023 to 03/24/2023, 0 (degrees) C, 4 days 03/27/2023 to 04/03/2023, 0 (degrees) C, 7 days 04/03/2023 to 04/10/2023, 0 (degrees) C, 7 days 11/13/2023 to 11/20/2023, 0 (degrees) C, 7 days 01/01/2024 to 01/08/2024, 0 (degrees) C, 7 days 02/12/2024 to 02/19/2024, 0 (degrees) C, 7 days 02/26/2024 to 03/04/2024, 0 (degrees) C, 7 days 03/12/2024 to 03/14/2024, 0 (degrees) C, 2 days 03/18/2024 to 03/25/2024, 0 (degrees) C, 7 days 04/01/2024 to 04/08/2024, between 0 and -5 (degrees) C, 7 days 04/08/2024 to 04/15/2024, between 0 and -5 (degrees) C, 7 days 04/15/2024 to 04/24/2024, between 0 and -5 (degrees) C, 7 days 04/22/2024 to 04/29/2024, between 0 and -5 (degrees) C, 7 days 04/29/2024 to 05/06/2024, between 0 and -5 (degrees) C, 7 days 05/06/2024 to 05/13/2024, between 0 and -5 (degrees) C, 7 days 05/13/2024 to 05/20/2024, between 0 and -5 (degrees) C, 7 days 05/20/2024 to 05/27/2024, between 0 and -5 (degrees) C, 7 days 05/27/2024 to 06/03/2024, between 0 and -5 (degrees) C, 7 days 06/03/2024 to 06/10/2024, between 0 and -5 (degrees) C, 7 days 06/10/2024 to 06/17/2024, between 0 and -5 (degrees) C, 7 days 06/17/2024 to 06

/24/2024, between 0 and -5 (degrees) C, 7 days 06/24/2024 to 07/01/2024, between 0 and -5 (degrees) C, 7 days 07/01/2024 to 07/08/2024, between 0 and -5 (degrees) C, 7 days 4. In an interview on 7/10/2024 at 14:20 hours, in the conference room, testing personnel (TP) 1 stated the internal refrigerator temperature is checked daily and a mechanism was not in place to ensure that the continuously monitoring chart recorder was accurately recording the temperature of the transfusion services storage refrigerator. Key: PRBC: Packed Red Blood Cells C: Celsius