Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0052243	10/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Tyler County Hospital Laboratory	1100 West Bluff Street, Woodville, 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 survey conducted October 4th and 5th, 2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on a review of hospital policy, patient transfusion records, and confirmed in interview, the laboratory failed to have a system in place to identify and document communication breakdowns for the identification and notification of suspected transfusion reactions for three of five random patients selected that met hospital transfusion reaction signs and symptoms from May to September 2022. The findings include: 1. Review of the Tyler County Hospital Policy/Procedure titled "Blood Administration", page three, had the following signs and symptoms (s/s) of a transfusion reaction a patient may exhibit while receiving blood product: "7. Watch for s/s of transfusion reactions which may include: 1. Elevation of temperature more than 2 degrees above baseline 2. Flank pain (pain in the lumbar area) 3. Nausea /vomiting 4. Unexplained oozing of blood at operative site 5. Unexplained blood in urine 6. Tachycardia or bracycardia (change in 10-15% from baseline) 7. Unexplained fall in blood pressure or rise in blood pressure (change in 10-15% from baseline) 8. Chills 9. Itching of skin 10. Hives 11. Edematous of skin vesicles 12. Edema of larynx 13. Shortness of breath, wheezing 14. Cyanosis 15. Symptoms of shock 2. A complete list of 29 patients transfused with blood products from May to September 2022 was provided and five random patient records were selected for review. The following three patients met the criteria for a transfusion reaction with no documentation of notification. Patient 10102345 Transfused 6/16/2022 Unit Number: W036522047214

	Pre-Transfusion (baseline) Blood Pressure (BP) at 21:25: 106/65 BP at 23:55: 134/62 Percent change from baseline: 26.4% increase decrease in systolic pressure Patient 10102797 Transfused: 6/24/2022 Unit Number: W036522038441 Pre-transfusion BP at 17:25: 159/65 BP at 20:45: 135/50 Percent change from baseline: 15.1% / 23.1% decrease in systolic/diastolic pressure Transfused: 6/25/2022 Unit Number: W036522037870 Pre -transfusion BP at 09:20: 147/56 BP at 12:50: 124/54 Percent change from baseline: 15.6% decrease in systolic pressure Patient 10104521 Transfused 8/14/2022 Unit Number: W036522073188 Pre-transfusion BP at 20:35: 170/84 BP at 8/15/2022, 00:09: 124/76 Percent change from baseline of 27% decrease in systolic pressure Transfused 8/16/2022 Unit Number: W036522060630 Pre-transfusion Blood Pressure (BP) at 10:15: 149/79 BP at 13:55: 100/61 Percent change from baseline: 32.8% / 22.8% decrease in systolic/diastolic pressure Surveyor queried on 10/4/2022 at 16:00, in the office, as to why the above instances weren't marked as a potential transfusion reaction by the observing nurse, and the laboratory or provider wasn't notified. The hospital nursing administrator stated that all the values above were normal patient values and wouldn't trigger an investigation. 3. In an interview on 10/4/2022 at 16:05, in the office, the laboratory manager stated that the laboratory had not participated in the transfusion record review of patients to identify and clarify communication issues for the identification and notification of suspected transfusion reactions Calculation: Percent Change: ((V2 - V1) / |V1|) x100 V2: Value 2 V1: Value 1 |V1|: Absolute value of V1
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory records, the Center for Medicare and Medicaid Services (CMS) form 116, and confirmed in an interview, the laboratory failed to perform calibration verification of three of three chemistry electrolytes on the Beckman Coulter DXc chemistry analyzer every six since it was last performed on November 2, 2021. The findings include: 1. Review of the laboratory policy titled "Chemistry Quality Control Program", section XVI "Linearity

	Protocol" stated: "Analyzer Measurement Range verification is validated by three point calibration. This must be done every six months using analyte specific calibrators." 2. Review of the linearity documents had the following three chemistry electrolyte ranges confirmed by calibration verification on November 2nd, 2021. NA - Sodium CL - Chloride K -Potassium Surveyor queried for the calibration verification documents for May 2022, six months after the November 2021 calibration verification, and none was provided. 3. Review of the CMS form 116, section VII. "Non-Waived Testing" listed an estimated annual volume for the specialty Chemistry at 77,021. 4. In an interview on 10/5/2022 at 11:40 hours, in the office, the laboratory manager confirmed that calibration verification had not been performed for the above chemistry electrolytes since November 2021.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (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. This STANDARD is not met as evidenced by: I. Based on a review of laboratory policy and procedure, laboratory documents, and confirmed in interview, the laboratory failed to perform and document monthly blood bank alarm checks for nine of nine months reviewed from January to September 2022. The findings include: 1. Review of the laboratory procedure titled "Blood Bank Alarm System, Temperature Check, Blood Bank Refrigerator Failure", stated: "Monthly, an alarm check will be performed, checking for low alarm, below 1.5*C and a high alarm above 5.6*C Documentation of this check is also on the monthly log, ER personnel will respond and it must be documented." 2. Review of the "Daily Blood Bank Temperature Charts" from January 2022 to September 2022 did not include the documentation for the alarm check at the bottom of the form. 3. In an interview on 10 /5/2022 at 10:50 hours, in the office, the laboratory manager confirmed that the alarm checks had not been performed, or documented, from January to September 2022. II. Based on a review of laboratory policy, blood bank temperature charts, and confirmed in interview, the laboratory failed to change the seven-day temperature monitoring chart every seven days for four out of twelve weeks reviewed in November 2021, April 2022, and September 2022. The findings include" 1. Review of the laboratory procedure titled "Blood Bank Alarm System, Temperature Check, Blood Bank Refrigerator Failure", stated: "A seven-day temperature monitor system is connected to the refrigerator, maintaining a temperature between 2* - 6*C (Celsius)." In an interview with the laboratory manager, it was clarified that the wheel charts were changed weekly by the night shift tech. 2. Review of the blood bank seven-day temperature monitoring wheels for November 2021, April 2022, and September 2022 had the following time frames where there was an overlap of seven days of continuous monitoring. "On 11/18/2021 at 0200 - Off 12/2/2021 at 0200" - Elapsed time 14 days. "On 04/07/2022 at 0200 - Off 04/15/2022 at 0200" - Elapsed time 8 days. "On 9/08 /2022 at 0200 - Off 09/15/2022 at 0200" - Elapsed time 8 days. "On 9/22/2022 at 0200 - Off 10/1/2022" - Elapsed time 9 days. 3. In an interview on 10/5/2022 at 11:20

	hours, in the office, the laboratory manager confirmed that the blood bank continuous monitoring wheel charts had not been changed after the seven-day period for the above instances.