Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0507433	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lamb Healthcare Center	1500 South Sunset, Littlefield, 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 May 8, 2024, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Review of policies and procedures, Transfusion Audits and interview of facility personnel found documentation was not audited by the director of nursing within 24 hours of the transfusion as defined in their own procedure for 9 of 9 patients receiving blood transfusions between March 1, 2024, and May 8, 2024. The findings included: 1. Review of the policy titled Blood and Blood Product Post Transfusion Audit Effective Date July 12, 2021) found on page 1 under the heading PROCEDURE: "1. Transfusion is ordered and performed by laboratory technologists. 2. All paperwork and E forms are filled out by laboratory technologists. 3. A sign out E-form is prepared for each unit of blood. 2. A two person sign out is performed by laboratory personnel and nurses, including either an R.N. or L.V.N., and laboratory personnel. Both nursing service and laboratory personnel must sign the e-form. 3. The nurse begins the transfusion and monitors the patient at the start, at 15 minutes, at 1 hour and at 2 hours. 4. At the completion of the transfusion and when all nursing forms are completed, a message is sent to the DON that a transfusion has been performed. 5. Each morning as either the DON or Assistant DON logs onto their computer a message is sent to them that a transfusion has occurred. 6. The message the DON receives, contains the Patient Demographics so at that time the DON will audit the transfusion nurses notes and vital signs, using the audit checklist within 24 hours of

the transfusion. 7. Those audit sheets will be monitored monthly by recording them in the QAPI minutes. Any problems with a transfusion can then be brought to medical staff attention." NOTE: directly quoted from procedure. 2. Review of Blood and Blood Product Transfusion Audit Checklist for 9 units transfused between March 1, 2024, and May 8, 2024, found: Audits were not reviewed within 24 hours for 9 patients. Patient 388529 - date of transfusion: 3.12.24, date/Time of Audit: 3.27.24 1639. 15 days had lapsed since transfusion. Patient 387260 - date of transfusion: (no date recorded), date/Time of Audit: 3.6.24 @ 1836. unknown number of days had lapsed since transfusion. Patient 388706 - date of transfusion: 3.16.2024, Date/Time of Audit: 3.27.24 @1712. 11 days had lapsed since transfusion. Patient 287260 - Date of Transfusion: 2.4.24, Date/Time of Audit: 3.6.24 @ 1905. 31 days had lapsed since transfusion. Patient 389585 - Date of Transfusion: 4.6.2024, Date/Time of Audit: 5.1.2024 @ 1630. 25 days had lapsed since transfusion. Patient 390216 - Date of Transfusion: 4.13.2024, Date/Time of Audit: 5.7.2024 @1327. 24 days had lapsed since transfusion. Patient 390216 - Date of Transfusion: 4.23.2024, Date/Time of Audit: 5.7.2024 @ 1131. 14 days had lapsed since transfusion. Patient 388238 - Date of Transfusion: (no date recorded), Date/Time of Audit: 3.20.2024 @ 1256. Unknown number of days had lapsed since transfusion. Patient 389849 - Date of Transfusion: 4.13.2024, Date/Time of Audit: 5.7.2024 @ 0959. 24 days had lapsed since transfusion. Further review of the Blood and Blood Product Transfusion Audit Checklist found documentation was incomplete or determined to not meet the defined requirements as defined in the Blood and Blood Products Administration policy for 5 of the 9 forms reviewed. Patient 388529 - Two nurse verification at bedside marked as not met. Patient education marked as not met. Patient 387260 - Consent form marked as not met. ID band and Blood Band on patient marked as not met. Two nurse verification at bedside marked as not met. Blood Transfusion Flowsheet utilized in CPSI marked as not met. 250 - ML Saline Flush available for use if reaction occurs marked as partially met. 15-minute vital signs marked as not met. Temperature increased marked as not met. Tachypnea change from baseline marked as not met. Systolic blood pressure decrease marked as not met. Patient 388706 - ID band and Blood Band on patient marked as partially met. Start of transfusion marked as not met. 15-minute check marked as not met' Q 1 hour Check marked as not met. Temperature increased marked as not met. Tachycardia marked as not met. Tachypnea change from baseline marked as not met. Systolic blood pressure decrease marked as not met. Patient 287260 - Consent form marked as not met. ID band and Blood Band on patient marked as not met. Two nurse verification at bedside marked as not met. Blood y-set marked as not met. 250 ml Saline Flush available for use marked as partially met. Blood Transfusion Flowsheet utilized in CPSI marked as not met. Start of Transfusion marked as not met. 15-minute check not documented. Q1 hour check not documented. Temperature increased not documented. Tachycardia not documented. Tachypnea change from baseline not documented. Systolic blood pressure decrease not documented. transfusion reaction educated not documented. Patient 389849 - Consent form marked as not met. ID band and Blood Band on patient marked as not met. Blood y-set marked as not met. 250 ml Saline Flush available for use marked as partially met. Blood Transfusion Flowsheet utilized in CPSI marked as not met. Temperature increased not documented. Tachycardia not documented. Tachypnea change from baseline not documented. Systolic blood pressure decrease not documented. transfusion reaction educated not documented. 3. During interview of the Director of Nursing conducted May 8, 2024, at 2:48 PM, she confirmed that Blood transfusion Audits were not being evaluated within 24 hours of the transfusion as defined in their own policy. She went on to clarify that if the forms were marked as "not met" this indicated that the information was not documented by nursing staff in the computer system. When asked if there was another means of documenting vital

	signs she stated there was not. Further interview of the director of nursing at 2:54 PM she confirmed that she was too busy to complete the audits within the 24-hour period, and if transfusion occurred during the weekend, it would not be done because she wasn't there.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory failed to have documentation of performing twice annual accuracy assessments in 2023 for one of one non-regulated analyte tested on the Diesse Mini Cube analyzer. Findings include: 1. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the non-regulated analyte Erythrocyte Sedimentation Rate (ESR) tested on the Diesse Mini Cube analyzer in 2023. 2. A review of the laboratory's test records revealed the laboratory performed a total of 218 ESR tests in 2023. 3. In an interview on 5/8/24 at 9:45 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's observation, a review of patient test records, and staff interview, the laboratory failed to ensure four of twenty-eight patient tubes had not exceeded their expiration dates prior to using them for patient testing on May 7, 2024. Findings include: 1. Surveyor observation of the specimen storage refrigerator in the laboratory on 5/8/24 at 11:35 a.m. revealed 28 lavender top patient specimen tubes had been used for testing on 5/7/24. 2. Further observation of the 28 lavender top patient specimen tubes revealed the following 4 tubes had exceeded their expiration date: Patient ID: 390830 Vacuette ref # 454209 Lot: B2207343 Exp: 10/31/23 Patient ID: 390831 Vacuette ref # 454209 Lot: B2207343 Exp: 10/31/23 Patient ID: 390832 Vacuette ref # 454209 Lot: B2207343 Exp: 10/31/23 Patient ID: 390833 Vacuette ref # 454209 Lot: B2207343 Exp: 10/31/23 3. A review of patient test records confirmed the 4 expired patient specimen tubes were used for Complete Blood Count (CBC) testing and values were resulted on 5/7/24. 4. In an interview on 5/8/24 at 11:35 a.m. in the conference room, after review of the records, the technical consultant confirmed the above findings.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not

	limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of laboratory policy, employee competency assessment records, and interview with the Laboratory Manager, the laboratory failed to assess problem solving skills on one of eleven testing personnel for the 2024 annual competency. The findings included: 1. Based on review of the laboratory's policy, "Competency and CLIA Competency Assessment", stated the following: "Competency is ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation." 2. Based on review of the competency assessment documentation for Testing Person 3 (as listed on the CMS-209 laboratory personnel report), the problem-solving quiz for hematology was blank and not completed. The quiz contained questions to assess problem solving skills in hematology, chemistry, microbiology,urinalysis, and immunohematology. 3. In an interview at 10:07 hours on 5/8/2024, the Laboratory Manager confirmed the assessment of problem-solving skills competency requirements were met by giving testing personnel quizzes and that Testing Person 3 had not completed the hematology competency quiz.