Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0682350	02/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Share Medical Center	800 Share Drive, Alva, OK	

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	The recertification survey was performed on 02/18,19,20/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and the technical consultant at the conclusion of the survey.
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: Based on a review of records, nursing policy, and interview with the laboratory manager, the facility failed to ensure written policies were followed for preventing transfusion reactions for four of four units of packed red-blood cells transfused. Findings include: (1) On 02/19/2025 at 11:55 am, the laboratory manager stated blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Blood Administration and Blood Component Administration" stated: (a) "Vital signs are taken immediately prior to infusing the blood" (b) "Every 15 minutes for four times, then" (c) "Every hour for the remainder of the transfusion." (3) A review of transfusion records for four units transfused, identified the policy had not been followed for four of four units as follows: (a) Unit #W091024426357 - The transfusion started on 01/27/2025 at 09:04 pm and ended at 11:30 pm. The 15 minute vital signs had not been taken as follows; (i) Between 09:19 pm and 09:49 pm. (b) Unit #W091025107315 - The transfusion started on 01/27/2025 at 11:58 pm and ended at 02:20 am. The 15 minute vital signs had not been taken as follows; (i) Between 12:15 am and 12:45 am. (c) Unit #W091024422261 - The transfusion started on 12/08/2024 at 01:50 am and ended at 03:30 am. The 15 minute vital signs had not

	been taken as follows; (i) Between 02:00 am and 02:30 am. (d) Unit #W091024423754 - The transfusion started on 01/03/2025 at 03:10 am and ended at 06:60 am. The 15 minute vital signs had not been taken as follows; (i) Between 03:25 am and 03:55 am. (4) The records were reviewed with the laboratory manager who stated on 02/19/2024 at 11:55 am, the vital signs had not been documented according to policy.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to label 24 of 24 aliquots of Bio-Rad Liquichek Specialty Immunoassay Control with the expiration date, and lot number of the contents. Findings include: (1) On 2/18 /2025 at 11:35 am, the laboratory manager stated that the laboratory performed parathyroid hormone testing on the Ortho Vitros 7600 analyzer; (2) Observation on 02 /18/2025 at 11:35 am identified a Styrofoam test tube flat with 1 ml sample cups and lids inside the Thermo Freezer; (3) Interview with the laboratory manager identified the cups contained frozen aliquots of Bio-Rad Liquichek Specialty Immunoassay Control materials; (4) A review of the product package insert stated, "once thawed, opened, and stored in tightly capped aliquot vials at -20 to -70 degrees Celsius, this product will be stable as follows: All analytes: 30 days"; (5) The findings were reviewed with the laboratory manager who on 02/18/2025 at 11:35 am stated the aliquots had not been labeled with the contents, expiration date, and lot number.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure reagents had not exceeded their expiration date for 2 of 62 days of patient testing. Findings include: (1) On 02/20/2025 at 09:50, the laboratory manager stated Crossmatch testing was performed in the laboratory which included ABO/Rh typing and antibody screening using the Ortho tube method; (2) On 02/20/2025, A review of quality control and patient testing records for testing performed from 01/01/2024 through 12/31/2024 identified expired Affirmagen and Coombs reagents had been used two of 62 days of testing reviewed as follows: (a) Ortho Affirmagen, lot #A770, expiration date 03/05/2024 with patient testing performed on 03/07/2024; (b) Ortho Coombs reagent, lot #K931, expiration date 01/30

	/2024 with patient testing performed on 02/01/2024. (4) This was reviewed with the technical consultant who stated on 02/20/2025 at 12:05 expired reagents had been used as indicated above.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the general supervisor, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for four of five emergency releases reviewed. Findings include: (1) On 02/19/2025 at 9:00 am, the general supervisor stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 02/19/2025 a review of the form titled, "Emergency Transfusion Request and Release" required an Emergency Transfusion Request and Release form be completed which stated, "As per an emergency request based upon (a) the stated allowable time before issuance for pre-transfusion testing, (b) the availibility of a patient's blood sample". The form included a space for the medical provider's signature; (3) A review of documentation of emergency issue identified the following for four of five patient records: (a) One unit of O negative packed red blood cells had been released to a patient on 01/03/2025. The "Emergency Transfusion Request and Release" form appeared to be signed by a mid-level provider and not a physician; (b) One unit of O negative packed red blood cells had been released to a patient on 12/10/2023. The "Emergency Transfusion Request and Release" form appeared to be signed by a mid-level provider and not a physician; (c) One unit of O positive packed red blood cells had been released to a patient on 02/01/2024. The "Emergency Transfusion Request and Release" form appeared to be signed by a mid-level provider and not a physician; (d) One unit of O negative packed red blood cells had been released to a patient on 11/22/2024. The "Emergency Transfusion Request and Release" form appeared to be signed by a mid-level provider and not a physician; (4) The documentation was reviewed with the laboratory manager who stated on 02/19/2025 at 9:00 am, the emergency releases had not been signed by a physician.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of six chemistry core proficiency testing events reviewed in 2023 and 2024. Findings include: (1) On 02/18/2025, a review of 2023 and 2024 proficiency testing events identified an attestation statement that had been signed after

	the graded evaluation was completed by the proficiency testing program for one of six chemistry core events reviewed: (a) Third Chemistry Core Event 2023 - The graded evaluation was completed on 09/28/2023 and the attestation statement had not been signed by the laboratory director until 10/14/2023. (2) The records were reviewed with the laboratory manager who stated on 02/18/2025 at 01:10 pm the attestation statements had not been signed timely as stated above.