Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472705	06/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Okeene Municipal Hospital	207 East F Street, Okeene, 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 05/31/2023 to 06/02/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant #2, and testing person #6 during an exit conference performed 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 chief nursing officer and technical consultant #2, the facility failed to ensure written policies were followed for preventing transfusion reactions for three of four units transfused. Findings include: (1) On 05/31/2023 at 11:00 am, technical consultant #2 stated the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)); (2) On 06/01/2023 a review of the hospital policy titled, "Blood Administration, Blood Product Administration" stated the following: (a) "Vital signs will be taken every 10 minutes during the first 30 minutes of infusion watching for transfusion reaction symptoms"; (b) After the first 30 minutes, the patient should be assessed frequently and vital signs taken every 30 minutes and documented on the vital signs flowsheet in EPIC for the duration of the transfusion". (3) A review of transfusion records for three patients identified the policy had not been followed for taking vitals for three of four units transfused as follows: (a) Unit #W091021433160 - The transfusion began on 12/01/2021 at 06:50 pm and was completed on 12/01/2021 at 10:12 pm: (i) Vitals Every Ten Minutes for the first 30 Minutes - There was no

	documentation vitals had been taken between 07:00 pm and 07:22 pm; (ii) Vitals Every 30 Minutes For the Duration of the Transfusion - There was no documentation vitals had been taken between 07:22 pm and 08:08 pm. (b) Unit #W091023411670 - The transfusion began on 02/23/2022 at 10:21 am and was completed on 02/23/2022 at 13:03 pm: (i) Vitals Every Ten Minutes for the first 30 Minutes - There was no documentation vitals had been taken between 10:22 am and 10:41 am; (ii) Vitals Every 30 Minutes For the Duration of the Transfusion - There was no documentation vitals had been taken between 10:49 am and 01:02 pm. (c) Unit #W091022240041 - The transfusion began on 07/06/2022 at 06:03 pm and was completed on 07/06/2022 at 08:17 pm: (i) Vitals Every 30 Minutes For the Duration of the Transfusion - There was no documentation vitals had been taken between 06:36 pm and 08:16 pm. (4) The findings were discussed with the chief nursing officer and technical consultant #2. Both stated on 06/01/2023 at 12:20 pm, the nursing policy had not been followed for taking vitals during patient transfusions.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #2, the laboratory failed to follow their written policy for documentation on the Emergency Release form for one of two patients receiving PRBC (Packed Red Blood Cells) in an emergency situation during the review period of January 2022 through the current date; and failed to follow their policy for documentation on the transfusion record for one of nine patient records reviewed from 08/01/2021 through the current date. Findings include: EMERGENCY RELEASE OF UNCROSSMATCHED BLOOD (1) On 05/31/2023 at 11:00 am, technical consultant #2 stated the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing, however in the event of an emergency, the laboratory would release uncrossmatched PRBC's according to laboratory policy; (2) On 06/01/2023 a review of the policy titled, "Emergency Issue of Non-Crossmatched Blood" required the laboratory complete "Authorization for Release of Uncrossmatched Blood in Emergency Situations" form, which contained a space to document the patient diagnosis; (3) A review of two patients receiving uncrossmatched blood during the review period of January 2022 through the current date identified the laboratory had not followed their policy for completing the form for one of two patients as follows: (a) Patient received blood on 08/19/2022 - The diagnosis had not been documented on the form. (4) The records were reviewed with technical consultant #2 who stated on 06/01/2023 at 01:20 pm, the laboratory had not followed their policy for completing the emergency release form. DOCUMENTATION ON TRANSFUSION RECORD (1) A review of blood bank policies and procedures on 06/01/2023, identified a policy titled, "Issuing Units" which stated the following: (a) "Before a unit of blood is release, transfusion service personnel must complete the following steps" (b) "Name and MRN of recipient must be recorded on the transfusion log". (2) A review of the transfusion record for patients tested from 08/01/2021 through the current date identified the MRN (medical record number) had not been documented on the log for one of nine patients reviewed

	(testing had been performed on 12/01/2021); (3) The findings were reviewed with technical consultant #2 who stated on 06/01/2023 at 01:20 pm, the MRN had not been documented as required.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for four of four function checks performed during the review period of November 2021 through the current date. Finding include: (1) On 05/31 /2023 at 10:35 am, technical consultant #2 stated the following: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Select Medical Product PSS centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) A review of the policy titled, "Centrifuge Maintenance" stated "All centrifuge RPM's will be calibrated at least every 6 months" and provided the acceptable limits as follows: (a) 1500 rpm +/- 100 rpm (3) A review of centrifuge records from November 2021 through the current date identified the centrifuge speed had not been checked at the speed urines were processed for four of four checks performed as follows: (a) 11/19/2021 - The speed had been checked at 2161 rpm; (b) 05/10/2022 - The speed had been checked at 2120 rpm; (c) 11/11/2022 - The speed had been checked at 2056 rpm; (d) 05/12/2023 - The speed had been checked at 2062 rpm. (4) The records were reviewed with technical consultant #2 who stated on 05/31 /2023 at 01:40 pm, the laboratory had not followed their policy.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to perform control procedures each day of blood bank testing for one of 24 days of patient testing reviewed from July 2022 through the current date. Findings include: (1) On 05/31/2023 at 11:00 am, technical consultant #2 stated the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing; (2) On 06/01/2023 a review of blood bank records

	for testing performed from July 2022 through the current date identified QC (quality control) had not been documented as performed for one of 24 days when patient blood bank testing had been performed as follows: (a) 02/22/2023 - A patient crossmatch had been performed (3) The records were reviewed with technical consultant #2 who stated on 06/01/2023 at 01:35 pm, the QC had not been documented as performed as stated above.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing for one of 24 patients reviewed. Findings include: (1) On 05/31/2023 at 10:30 am, technical consultant #2 stated the following: (a) Blood gas testing (pH, pCO2, pO2) was performed on the Opti CCA TS2 analyzer; (b) Three levels of quality control (QC) material were performed each eight hours of patient testing. (2) A review of QC and patient records for testing performed from July 2022 through the current date identified that QC testing had not been performed each eight hours of patient testing (three levels had not been performed on the day of patient testing) for one of 24 patients reviewed (Date of testing was 02/22/2023); (3) The records were reviewed with technical consultant #2 who stated on 05/31/2023 at 03:15 pm, QC testing had not been performed each eight hours of patient testing.
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). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with technical consultant #2, 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 one of two emergency releases reviewed. Findings include: (1) On 05/31 /2023 at 11:00 am, technical consultant #2 stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 06/01/2023 a review of the policy titled, "Emergency Issue of Non-Crossmatched Blood" required an Emergency Release form be completed which stated, "The clinical situation of this patient requires the transfusion of uncrossmatched or partially crossmatch blood. I understand that the crossmatch will be completed as soon as possible". The form included a space for the Physician's

	signature; (3) A review of documentation of emergency issue for two patients identified the following for one of two patient records: (a) One unit of O negative packed red blood cells had been released to a patient on 08/19/2022 at 11:21 am. The "Authorization for Release of Uncrossmatched Blood in Emergency Situations" form appeared to be signed by a physician's assistant and not a physician. (4) The documentation was reviewed with technical consultant #2 who stated on 06/01/2023 at 03:25 pm, the ER release had not been signed by a physician.