Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472771	04/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Harper County Community Hospital	1003 Hwy 64 North, Buffalo, 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 04/22,23/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager at the conclusion of the survey.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 04/22/2021 at 08:35 am, the laboratory manager stated the following to the surveyor: (a) The Sysmex CA-620 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing; (b) The following reagent lot numbers were put into use on 12/11/2020: (i) PT - Innovin reagent, lot #549755B (ii) PTT - Actin reagent, lot #562628A (2) The surveyor reviewed the manufacturer's instructions contained in the "Siemens Sysmex CA-600 Installation Guide" for implementing new reagents, which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number

	reagents simultaneously or within 1 our of each other"; (v) "Calculate Linear Regression statistics". (3) The surveyor reviewed the records for the lot changes with the following identified: (a) PT Innovin reagent (i) Method Correlation - The records showed the laboratory had used 20 abnormal samples, but they did not span the Reportable Range of the assay. The laboratory had used samples that ranged from 12.9-44.8 and the laboratory's reportable range was 8.9-138.5. (b) PTT Actin reagent (i) Method Correlation - The records showed the laboratory had used 20 abnormal samples, but they did not span the Reportable Range of the assay. The laboratory had used samples that ranged from 28.8-41.2 and the laboratory's reportable range was 22.7-224.10. (4) The surveyor reviewed the findings with the laboratory manager who stated on 04/22/2021 at 03:00 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the demonstrated reportable range was utilized for Hemoglobin A1c testing. Findings include: (1) On 04/22/2021 at 08:40 am, the laboratory manager stated to the surveyor the laboratory began performing Hemoglobin A1c testing using the Afinion 2 Hemoglobin A1c DX assay on 06/30/2020; (2) The surveyor reviewed the performance specification records and identified the laboratory had demonstrated a reportable range of 4.99-12.26; (3) The surveyor then reviewed the records with the laboratory manager and asked for documentation to ensure the laboratory was utilizing the reportable range that had been demonstrated by the laboratory. The laboratory manager provided documentation and stated the to the surveyor on 04/22/2021 at 3:30 pm, the laboratory was using the manufacturer's reportable range of 4.0-14.1 instead of the reportable range of 4.99-12.26 that had been demonstrated by the laboratory.
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: Based on a review of records, policies and procedures, AABB Technical Manual, and

	interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions for 2 of 9 alarm checks. Findings include: (1) On 04/22/2021 at 08:40 am, the laboratory manager stated to the surveyor units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (2) The surveyor reviewed the policy titled, "Blood Bank Alarm Test" which stated, "The alarm system should be tested quarterly" and provided acceptable results for the low and high alarm checks and stated: (a) "The high alarm should sound at 5.5 C +/- 1.0 C" (b) "The low alarm should sound at 1 C +/- 1.0 C" (3) Based on the policy, the surveyor documented the ranges the laboratory allowed for the alarm checks which were: (a) The laboratory defined an acceptable high alarm check as 4.5 degrees C (Centigrade) to 6.5 degrees C; (b) The laboratory defined an acceptable low alarm check as 0 degrees C to 2.0 degrees C. (4) As a reference, the surveyor reviewed the AABB (American Association of Blood Banks) Technical Manual, Fifteenth Edition on page 184 under the heading "Refrigerated Storage" which stated, "Blood must be stored only in refrigerators that, by desing and capacity, maintain the required blood storage temperatures of 1 to 6 C throughout their interior space"; (5) Based on the above, the surveyor determined the acceptable results for the alarm checks documented in the laboratory's policy titled, "Blood Bank Alarm Test" allowed for temperatures beyond the range of 1.0 to 6.0 degrees C. The surveyor then reviewed alarm checks performed during 2019 through the current date. The high alarm check results sounded at temperatures warmer than 6.0 degrees C (the warmest allowable temperature for blood products) for 2 of 9 alarm checks performed as follows: (a) 09/20/2019 - The temperature for the high alarm check sounded at 6.5 degrees C; (b) 06/05/2020 - The temperature for the high alarm check sounded at 6.2 degrees C. (6) The surveyor reviewed the records with the laboratory manger who stated the acceptable ranges for the alarm checks, as stated in the policy, were not correct; and the temperature the alarm sounded for the high alarm checks above were not acceptable.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 written policies and interview with the laboratory manager and director of nursing, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 1 of 4 units of packed red blood cells. Findings include: (1) On 04/22/2021 at 08:40 am, the laboratory manager stated to the surveyor the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 04/23/2021, the surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Transfusion Record" stated, "Obtain vital signs immediately prior to start of

	administration of the product, 15 minutes after start of the product, 30 minutes after the start of the product for one hour, and then hourly until discontinuation of unit"; (3) The surveyor then reviewed records for 4 units of PRBC's (Packed Red Blood Cells) that had been transfused between 07/24/2020 through 02/06/2021 for 4 patients. It was identified the vitals had not been taken hourly after the first hour until discontinuation of the unit as follows: (a) Patient #14763 - Transfused with 1 unit of PRBC's (unit #W091021110754) on 02/05,05/2021. The vitals had not been taken between: (i) 02/05/2021 at 08:30 pm and 10:09 pm; (ii) 02/05/2021 at 11:20 pm and 02 /06/2021 at 01:57 am. (4) The surveyor reviewed the findings with the laboratory manager and the director of nursing. Both stated on 04/23/2021 at 11:00 am, the vitals had not been taken hourly as specified above.