Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473136	10/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Hospital Claremore	1202 N Muskogee Pl, Claremore, 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 10/19,20,21/2020 The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, director of quality, chief executive officer, human resource director, laboratory manager, and testing person #3 during an exit conference performed 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/technical consultant, the laboratory failed to follow the manufacturer's instructions for performing ACT testing for 2 of 6 patients. Findings include: (1) On 10/19/2020 at 11:30 am, the laboratory manager/technical consultant stated to surveyor #1 ACT (Activated Clotting Time) testing was performed on the iSTAT 1 analyzer, using the ACT Celite test cartridge; (2) On 10/20/2020, surveyor #2 reviewed the manufacturer's instructions for the assay. Under the heading "Time to Test" the instructions stated, "The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer"; (3) Survyeor #2 reviewed 6 patient ACT reports from 08/03/2020 through 09/24/2020 which confirmed the laboratory had not followed the manufacturer's instructions for testing the sample immediately for 2 of 6 patients as follows: (a) Patient tested on 08/11/2020 - The specimen had been collected at 01:31 pm and received at 01:51 pm (10 minutes); (b) Patient tested on 09/24/2020 - The specimen had been collected at 10:39 and received at 11:55 (76 minutes). (4) Surveyor #2

	reviewed the records with the laboratory manager/technical consultant, who stated on 10/20/2020 at 01:05 pm, the manufacturer's instructions had not been followed for the two patients 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 demonstrate the reportable range for 1 of 1 new test systems. Findings include: (1) On 10/19/2020 at 11:30 am, the laboratory manager/technical consultant stated to surveyor #1 the laboratory began performing ACT (Activated Clotting Time) testing using the iSTAT 1 analyzer on 04/13/2019; (2) Surveyor #2 reviewed the performance specification records and could not locate evidence the reportable range had been demonstrated; (3) On 10/20/2020, surveyor #2 reviewed the records with the laboratory manager/technical consultant and asked if there was documentation to prove the reportable range had been demonstrated for the new test system. The laboratory manager/technical consultant stated on 10/2020 at 01:05 pm, there was no documentation to prove the reportable range had been demonstrated.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager/technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 2 of 2 analyzers. Findings include: (1) On 10/19/2020 at 11:30 the laboratory manager /technical consultant stated the following to surveyor #1: (a) *CMP, Ammonia, Amylase, Cholesterol, Creatine Kinase, HDL (High Density Lipoprotein), Triglycerides, Alcohol, Iron, Lactate, Lipase, Magnesium, Uric Acid, UIBC (Iron Binding Capacity), Acetaminophen, Direct Bilirubin, Digoxin, and Salicylic Acid testing were performed on the Beckman Coulter AU 480 analyzer, denoted by the laboratory as Righty; (b) *CMP, Ammonia, Amylase, Cholesterol, Creatine Kinase, HDL (High Density Lipoprotein), Triglycerides, Lactate, Lipase, Magnesium, Uric Acid, Carbamazepine, Direct Bilirubin, Gentamicin, Phenytoin, Vancomycin,Valproic Acid,*Urine Drug Screen, CSF (Cerebral Spinal Fluid) Glucose, CSF Total Protein testing were performed on the Beckman Coulter AU 480 analyzer, denoted by the laboratory as Lefty. (2) On 10/20/2020, surveyor #2 reviewed the manufacturer's

	maintenance requirements as stated on the manufacturer's maintenance logs. The following was required every three months: (a) Replace the Roller Tubes for MID Solution dispense and Mixture Aspiration (b) Replace the Pinch Valve Tubing (3) Surveyor #2 then reviewed maintenance records for both analyzers for 13 months (September 2019 through September 2020). The every three month maintenance had not been documented as performed as follows: (a) Righty - Between 11/04/2019 and 08/04/2020 (b) Lefty - Between 11/04/2019 and 08/04/2020 (4) Surveyor #2 reviewed the records with the laboratory manager/technical consultant, who stated on 10/20 /2020 at 04:03 pm, the above maintenance had not been documented as performed. *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein *Urine Drug Screen - Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Ecstasy, Methadone, Opiate, Phencyclidine
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, policies and procedures, and interview with the laboratory manager/technical consultant, the laboratory failed to ensure the urine, blood bank, and coagulation centrifuges were functioning properly. Findings include: URINE CENTRIFUGE (1) On 10/21/2020 at 10:00 am, the laboratory manager /technical consultant stated to surveyor #1 urine sediment examinations were performed in the laboratory. The specimens were processed in the Clay Adams Dynac centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) Surveyor #1 reviewed the function check policy which required speed and timer checks be performed on the centrifuge annually; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2019 and to date in 2020, with the following identified: (a) There was no documentation to prove the centrifuge speed and timer had been checked in 2019; (b) Although the speed had been checked at 1414 rpm on 10/19 /2020, the timer check had been documented as "OK" and did not indicate that the timer was checked at 5 minutes, which was the time the laboratory processed urines. (4) Surveyor #1 reviewed the findings with the laboratory manager/technical consultant, who stated on 10/21/2020 at 2:30 pm, the centrifuge function checks had not been performed as indicated above. BLOODBANK CENTRIFUGE (1) On 10/21 /2020 at 10:15 am, the laboratory manager/technical consultant stated to surveyor #1 the laboratory used the Ortho MTS centrifuge for performing Antibody Screen testing at a speed of 895 +/-25 rpm for 10 minutes; (2) Surveyor #1 reviewed the function check policy which required speed and timer checks be performed on the centrifuge annually; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2019 and to date in 2020, with the following identified: (a) There was no documentation to prove the centrifuge speed and timer had been checked in 2019; (b) Although the

	speed had been checked at 923 rpm on 10/19/2020, the timer check had been documented as "OK" and did not indicate that the timer was checked at 10 minutes, which was the time the laboratory processed specimens. (4) Surveyor #1 reviewed the findings with the laboratory manager/technical consultant , who stated on 10/21/2020 at 3:00 pm, the centrifuge function checks had not been performed as indicated above. COAGULATION CENTRIFUGES (1) On 10/21/2020 at 10:30, the laboratory manager/technical consultant stated to surveyor #1 the following centrifuges were used to process patient specimens for PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing: (a) Heraeus Medical Megafuge - Specimens processed at a speed of 3600 rpm for 10 minutes; (b) Hettich Universal centrifuge - Specimens processed at a speed of 4500 rpm for 10 minutes; (c) Horizon Mini B centrifuge - Specimens processed at a speed of 3600 rpm for 10 minutes. (2) Surveyor #1 reviewed the function check policy which required speed and timer checks be performed on the centrifuge annually; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2019 and to date in 2020, with the following identified: (a) There was no documentation to prove the speed and timer of the centrifuges had been checked in 2019; (b) Checks Performed 10/19/2020: (i) Heraeus Medical Megafuge - Although the speed had been checked at 3636 rpm, the timer check had been documented as "OK" and did not indicate that the timer was checked at 10 minutes, which was the time the laboratory processed specimens; (ii) Hettich Universal centrifuge - Although the speed had been checked at 4545 rpm, the timer check had been documented as "OK" and did not indicate that the timer was checked at 10 minutes, which was the time the laboratory processed specimens; (iii) Horizon 642 B centrifuge - Although the speed had been checked at 3400 rpm, the timer check had been documented as "OK" and did not indicate that the timer was checked at 10 minutes, which was the time the laboratory processed specimens. (4) Surveyor #1 reviewed the findings with the laboratory manager/technical consultant , who stated on 10/21/2020 at 3:10 pm, the centrifuge function checks had not been performed as indicated above.
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 the laboratory manager/technical consultant, the laboratory failed to perform a negative and positive control material 1 of 4 days of patient Mononucleosis testing. Findings include: (1) On 10/19/2020 at 11: 30 am, the laboratory manager/technical consultant stated the following to surveyor #1: (a) The laboratory began using the Cardinal Health Mono II Rapid test kit and serum or plasma samples to perform Mononucleosis testing on 04/16/2020; (b) Negative and Positive QC (Quality Control) materials were performed each day of patient testing. (2) Surveyor #2 reviewed QC and patient testing records from 08/05 /2020 through 10/13/2020. The review showed negative and positive QC materials had not been performed 1 of 4 days of patient testing reviewed. The specific day was

	09/24/2020; (4) Surveyor #2 reviewed the records with the laboratory manager /technical consultant, who stated negative and positive QC materials had not been performed each day of patient testing.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratoratory manager/technical consultant, the laboratory failed to ensure quality control was tested in the same manner as patient specimens for 36 of 36 days of negative AHG quality control testing. Findings include: (1) On 10/19/2020 at 11:30 am, the laboratory manager/technical consultant stated the following to surveyor #1: (a) Antibody Screen testing, to detect unexpected antibodies in patient plasma, was performed using the Ortho AHG (Anti Human Globulin) Anti-IgG gel card and 0.8% Selectogen Reagent Red Blood Cells I and II; (b) Positive and Negative QC (Quality Control) testing were performed each day for the AHG Anti-IgG gel card. (2) On 10 /20/2020, surveyor #2 reviewed QC records for 36 days of testing performed from 07 /17/2020 through 07/31/2020; and 09/03/2020 through 09/30/2020. The QC documentation for the negative AHG QC consisted of Selectogen Reagent Red Blood Cells I or II added to the AHG well of the gel card. There was no documenation a plasma based material had been added to the well in addition to the Selectogen Reagent Red Blood Cell I or II; (3) Surveyor #2 asked the laboratory manager /technical consultant to explain what was added to the wells of the gel card when a patient Antibody Screen was performed. The laboratory manager/technical consultant stated on 10/20/2020 at 02:30 pm patient Antibody Screen testing consisted of patient plasma and 0.8% Selectogen I or II added to the AHG gel card; (4) Surveyor #2 reviewed the QC records with the laboratory manager/technical consultant and asked if a plasma based material was utilized in the procedure when a negative AHG control was performed. The laboratory manager/technical consultant stated on 10/20/2020 at 02:45 pm, the negative AHG QC consisted of 0.8% Selectogen I or II added to the AHG gel card and did not include a plasma based material. Therefore, surveyor #2 determined QC had not been tested in the same manner as patient specimens for the following 36 days of QC testing: (a) July 2020 - days 17,18,19,20,28,29,30,31 (b) September 2020 - days 03,04,05,06,07,08,09,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30 NOTE: The interpretive guidelines at D5465 (493.1256) state "Control materials of a similar matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases."
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) 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, and interview with the laboratory manager/technical consultant, the laboratory failed to test one control material each 8 hours of operation when performing manual counts using a hemacytometer for 1 of 14 days. Findings include (1) On 10/19/2020 at 11:30 am, the laboratory manager/technical consultant stated to surveyor #1 spinal fluid cell counts for White Blood Cells and Red Blood Cells were performed in the laboratory using a hemacytometer; (2) Surveyor #1 reviewed the patient and quality control log for patient testing performed from 04/22 /2019 through 09/30/2020. There was no evidence a control material had been performed 1 of 14 days of patient testing. The specific day was 07/07/2019; (3) Surveyor #1 reviewed the records with the laboratory manager/technical consultant, who stated on 10/19/2020 at 1:00 pm, there was no evidence that a control had been tested on 07/07/2019.
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,and interview with the laboratory manager, the laboratory failed to ensure that blood products were stored under appropriate conditions for 1 of 8 alarm checks. Findings include: (1) On 10/19 /2020 at 11:30 am, the laboratory manager/technical consultant stated to surveyor #1 units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (2) Surveyor #1 reviewed the policy titled, "Blood Bank Refrigerator Alarm Check" which stated, "High and Low temperatures of activation should be checked quarterly." (3) Surveyor #1 reviewed Blood Bank Refrigerator Alarm Check records between 01/25/2019 through 10/21/2020 (last day of the survey) and identified that quartely alarm checks had not been performed between 06/29/2020 and 10/21/2020; (4) Surveyor #1 reviewed the records with the laboratory manager /technical consultant who stated on 10/21/2020 at 10:45 the Blood Bank Refrigerator Alarm Checks had not been performed for as stated above.
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 /technical consultant, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 1 of 5 packed red blood cell units. Findings include: (1) On 10/19/2020 at 11:30 am, the laboratory manager/technical consultant stated to surveyor #1 units of packed red blood cells, which were stored in the blood bank refrigerator, were used for patient transfusions; (2) Surveyor #2 reviewed the Nursing Policy and Procedure regarding blood administration. The policy titled, "Blood Product Administration" stated the following: (a) "7. Obtain and document patient's temperature and vital signs (not more than 15 minutes) prior to administration, 15 minutes after initiation, then hourly until transfused. A final set of vitals signs will be obtained within 15 minutes after completion of transfusion." (3) Surveyor #2 reviewed transfusions on 01/03/2020, 02/03/2020, 02/25/2020, and 04/28 /2020 (a total of 5 units) and identified the following: (a) Stop time of the infusion (1) Patient # 0000257005 - Transfused with 1 unit of PRBCs (unit# W204920455535) on 02/25/2020. There was no documentation indicating the stop time of the infusion. (4) The above transfusion record was reviewed with the laboratory manager/technical consultant on 10/20/2020 who stated at 03:35 pm the record did not follow the blood administration policy as indicated above.