Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475204	10/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hillcrest Hospital/Henryetta	2401 W Main St, Henryetta, 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 10/17,18,19,20/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, technical consultant, and laboratory manager during an exit conference performed at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory director failed to assess the competency of the general supervisor based on the position responsibilities as listed in subpart M. Findings include: (1) A review of the laboratory policy and procedure manual titled competency assessment delegation statesd "The performance of the duties of the general supervisors will be assessed annually by either the laboratory director or technical consultant and reviewed and approved by the laboratory medical director. The assessment is documented with a checklist and reviewed and signed by the technical consultant and laboratory medical director." (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of October 2021 through the current date identified competencies, based on job responsibilities, had not been performed for general supervisor #1 listed on the CMS-209; (3) The findings were reviewed with the technical consultant who stated on 10/18/2023 at 01:23 pm that competencies were not performed for general supervisor #1 during the review period of October 2021 to the current date.

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 #1 the laboratory failed to follow their written policy for documentation on the transfusion service record for 14 of 14 days of patient testing during the review period of May 12, 2023 through the current date. Findings include: THERAPEUTIC PHLEBOTOMY (1) On 10/18/2023 at 10:00 am, general supervisor #2 stated the laboratory performed therapeutic phlebotomies according to laboratory policy; (2) On 10/18/2023 a review of the policy titled, "Therapeutic Phlebotomy"" required the laboratory document on the bloodbank worksheet the following; (i) Patient Name (ii) Date and Time (iii) Approximate amount of blood removed (iv) Phlebotomist initials (v) On blood bank worksheet only, document "unit incinerated" (3) A review of therapeutic phlebotomies identified the laboratory had not followed their policy for completing the worksheet for 6 of 11 patients as follows: (a) 10/17/2023, 09/25/2023, 08/23/2023 and 05/12/2023 - The time and initials had not been documented on the worksheet. (b) 07/27/2023 and 06/05/2023 - The time and "unit incinerated" had not been documented on the worksheet. (4) The records were reviewed with general supervisor #2 who stated on 10/18/2023 at 10:00 am, the laboratory had not followed their policy for documenting therapeutic phlebotomies on the worksheet. BLOOD BANK (1) A review of blood bank policies and procedures on 10/18/2023, identified a policy titled, "Blood Bank - Daily Record Keeping Procedures" which stated the following: (a) "Record all work done on the blood bank worksheet. 1. Include: Name, date, ID#, and physician for each unit being crossmatched. 2. Record ABO, Rh and antibody screen results on first line. 3. Include donor type for each unit crossmatched. 4. Record patient blood bank armband number using a blood bank sticker. 5. Mark each unit as compatible or incompatible and record tech initials and component for every unit and document ID# of unit(s). 6. Mark incompatibilities in red on worksheet". (2) A review of the transfusion worksheet for patients tested from 05/12 /2023 through the current date identified the following; (i) 07/28/2023, 07/25/2023, 07 /24/2023, 07/20/2023, 06/29/2023 and 05/25/2023 - No tech initials was documented on the transfusion worksheet. (ii) 08/10/2023 - the crossmatch interpretation was not documented for three of three units. (iii) 10/17/2023 - Antibody screen interpretation was not documented. (3) The findings were reviewed with general supervisor #2 who stated on 10/18/2023 at 10:00 am, the worksheet had not been documented as required.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required during the review period of January 2023 through the current date. Findings include: (1) On 10/20/2023 at 11:15 am, observation of the contents of the CTFI Blood Bank freezer identified the following materials: (a) One box of reconstituted Access PCT (Procalcitonin) Calibrators, lot #338315 (b) Ten bottles of Bio-Rad Cardiac Markers Plus control materials level one, lot #87851 (c) 11 bottles of Bio-Rad Cardiac Markers Plus control materials level two, lot #87852 (d) 11 bottles of Bio-Rad Cardiac Markers Plus control materials level three, lot #87853 (2) A review of the storage requirements for the above materials identified the following: (a) Access PCT Calibrator package insert stated, "Use reconstituted calibrators within 4 hours when stored at 20-25 degrees C. Otherwise, freeze at -30 to -15 degrees C for up to 90 days"; (b) The storage requirement, as stated on the bottles, for the Bio-Rad Cardiac Markers control materials were -70 to -20 degrees C (Centigrade). (3) A review of temperature records from January 2023 through the current date identified that, although temperatures had been documented each day, the log did not define the acceptable limits for storage of the materials (for the above materials, the acceptable limits should be -30 to -20 degrees C); (4) The records were reviewed with the laboratory manager who stated on 10/202/2023 at 12:40 pm, the laboratory had not defined the acceptable storage temperatures to ensure the materials were stored as required by the manufacturer.