Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453273	03/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hamilton County Hospital	700 Huser Street, Syracuse, KS	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Quality Assurance (QA) procedures, the lack of available (QA) documents, and interview with staff reveals that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings: 1. The laboratory failed to follow their Quality Assurance Plan ,written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. On March 20, 2019 at 1130 an interview with the Technical Consultant #1 confirmed that the laboratory had not performed the monitors outlined in the current Quality Assurance Plan.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: A review of calibration verification records for the Sysmex XS-1000i, and interview with staff revealed that the laboratory failed to perform calibration verification once every six months. Finding were as follows 1. Review of the Sysmex XS-1000i calibration verification documentation revealed the laboratory failed to perform calibration verification at least once every six months. The laboratory performed a calibration verification on January 12, 2018 but failed to perform the calibration verification that was due in July 2018. This was confirmed in interview with Testing person #2 on March 20, 2019 at 11:00 hrs.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Review of quality control (QC) records from 2018 and interview with the Technical Consultant #1 and General Supervisor #2 at 12:30 PM on March 20, 2019 revealed that the laboratory failed to perform QC as required. The laboratory failed to perform quality control at least once a day of patient testing for quantitative procedures, include two control materials of different concentrations. The findings: 1) The Troponin cartridges for the ISTAT require quality control at least once a day of patient testing with two control materials of different concentrations. 2) QC records indicate that external, liquid controls are tested monthly and with each new shipment and lot number of cartridges. 3) No Individualized Quality Control Plan has been performed to allow the laboratory to reduce the frequency of QC performance.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: 1. A review of manufacturer's instructions for Innovin , quality control and quality assessment records for coagulation, observation of the laboratory's equipment, and interview with staff on March 20, 2019 revealed that the laboratory did not follow manufacturer's instructions for International Normalized Ratio (INR) . Findings were as follows: a. Manufacturer's instructions from CA 600 for the determination of INR state: "The normal PT is defined as the mean of the normal range and must be specifically determined for each lot of Innovin, with the specific instrument/technique used for patient testing".At the time of the survey the laboratory failed to produce a normal patient mean for the calculation of the INR b. Quality control and quality assessment records for Sysmex CA600 coagulation analyzer on March 20, 2019 did not include determination of the Prothrombin Time (PT) for patient normal range for the current lot of Innovin in use. Therefore the accuracy or reliability can not be verified.
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: Review of 2018 blood bank function check records and interview with staff reveals that laboratory failed to regularly inspect the alarm system(s) according to its established policy. Findings: 1. According to the current policy for "GEM BB Refrigerator Operation and Maintenance" and the policy in place for 2018 named "Blood Bank Refrigerator Alarm Testing". Quarterly checks of the alarm system should be verified to ensure the system is functioning properly. 2. The laboratory provided documentation of one alarm check on December 7, 2018 but failed to provide documentation of the other three alarm checks for 2018. Interview on March 20, 2019 at 1145 with the technical consultant #1 confirmed that there were no records of the three missing alarm checks.