Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0046777	09/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hiawatha Hospital Association	300 Utah St, Hiawatha, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) documentation and interview, the laboratory failed to verify the accuracy of hematology and microbiology analytes that were assigned a ungraded proficiency testing score. Findings Include: 1. Review of the laboratory's 2018 and 2019 API PT documentation for hematology and microbiology found the following ungraded results: Hematology/Coagulation: 2018 - 2nd Event: Received "Grade" of "Not Graded" Blood Cell Identification: BCI-13, BCI-14, BCI-10 Microbiology 2018 - 2nd Event: Received "Grade" of "Not Graded" Molecular Resist. Genes-Blood: BCP-07 Microbiology 2019 - 1st Event Received "Grade" of "Not Graded" Urine Identification: UR-03 2. Review of the laboratory's PT review and corrective action forms failed to find any documentation demonstrating a self-assessment or self-grade of the "Not Graded" samples. 3. Technical Supervisor (TS) #2 stated that all "Not Graded" results were reviewed by the laboratory director and TS #2, but did not document the review, self-assessment, or self-grade performed. The interview occurred Septemmber 5, 2019 at 11am.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon a review of the laboratory procedures and policy manual, and interview, the laboratory failed to define by written procedure: reference intervals (normal values) for the Sysmex-XN-1000i Hematology analytes: white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin, hematocrit and platelet count. Findings include: 1. The surveyor requested a test procedure that included written information of reference intervals (normal values) for the Sysmex-XN-1000i Hematology analytes. What was provided was the "Instructions for Use" (IFU) on the analyzer. This electronic document did not contain the reference ranges for: white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin, hematocrit and platelet count. 3. The TS #2 could not provide a written procedure with reference intervals (normal values) for: white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin, hematocrit and platelet count. 4. The TS #2 confirmed that the laboratory failed to have written procedures for reference intervals (normal values) for the Sysmex-XN-1000i Hematology analytes: white blood cell (WBC) count, red blood cell (RBC) count, hemoglobin, hematocrit and platelet count. Interview occured Septemmber 5, 2019 at 2:30 PM.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a lack of available documentation and interview, the laboratory failed to have procedures approved, signed, and dated by the laboratory director before use. Findings include: 1. Upon review of the laboratory procedures, the current laboratory director did not approve, sign, and date the laboratory procedures for automated hematology. 2. The Laboratory Director confirmed that the laboratory failed to have procedures for automated hematology approved, signed, and dated by the laboratory director before use.. Interview occured Septemmber 5, 2019 at 2:30 PM.
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 review of 2018 and 2019 thermometers records and interview, the laboratory fails to have a function check for all the thermometers used for temperature monitoring. Findings include: 1. Certificates of accuracy were available only for thermometers used for blood product storage. Thermometers for specimen and reagent storage, culture incubation, blood product thawing, and environmental monitoring had no records of function checks available at the time of survey. 2. TS #2 stated that the laboratory failed to have a function check for all the thermometers used for temperature monitoring. Interview occurred on September 5, 2019 at 2:30 pm.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the MedTox Profile V package insert, individualized quality control plan (IQCP), QC records, and interview, the laboratory failed to have an IQCP for the urine medical drug screen performed using the MedTox Profile V test system. Findings include: 1. MedTox Profile V is classified as a non-waived test, requiring quality control (QC) to be performed each day of patient testing. 2. The package insert for the MedTox Profile V requires QC to be performed at least weekly. 3. Laboratory QC records show QC performed according to manufacturer's requirements. 4. No IQCP plan in use for MedTox Profille V to allow QC to be performed less than each day of patient testing. 5. Interview with TS #2 on September 5, 2019 at 11:00 AM confirmed the laboratory failed to have an IQCP plan for the urine medical drug screen performed using the MedTox Profile V test system.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must

	have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of chemistry Siemens Dimension EXL 200, Abbot i-Stat and hematology Sysmex XN-1000i procedures, lack of correlation records and interview, the laboratory failed to evaluate and define the relationship between test results using different methodologies and instruments. Findings include: 1. Review of chemistry analytes sodium, potassium, chloride, CO2, BUN, creatinine and glucose showed they are performed on the Siemens Dimension EXL 200 and the Abbot iStat. No procedure was available on how to evaluate and define the relationship between the chemistry test results. 2. Review of hematology analyte hematocrit showed it is performed on the Abbot iStat and the Sysmex XN-1000i. No procedure was available on how to evaluate and define the relationship between the hematology test results. 3. No correlation tesing records for in 2018 and to date September 5, 2019 were made available at the time of survey. 4. Interview with the TS #2 on September 5, 2019 at 2: 00 PM confirmed the laboratory failed to evaluate and define the relationship between test results for sodium, potassium, chloride, CO2, BUN, creatinine, glucose and hematocrit.