Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0679679	01/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Horton Community Hospital	240 West 18th Street, Horton, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the phlebotomy area located within the laboratory and interview with the technical supervisor #2, the laboratory failed to store glucose tolerance testing supplies appropriately and failed to provide a safe environment in which laboratory personnel and patients are protected from physical,chemical and biological hazards. Findings: 1. Observation of the laboratory showed one phlebotomy chair located directly within the laboratory next to testing analyzers. Venous blood draw and throat culture swab collection procedures occurred while testing personnel performed specimen testing. 2. Observation of 2 bottles of glucose tolerance drink for patient consumption was located in the laboratory cabinet. 3. Interview with the technical supervisor #2 on January 4,2019 at 11:30 AM confirmed the laboratory failed to ensure laboratory personnel and patients were protected from physical, chemical and biohazard materials.
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 on review of the procedure manual and interview with the technical supervisor #2, the laboratory failed to include reference intervals (normal values) for urine sediment testing. Findings: 1. Review of the procedure manual revealed a lack of normal values for urine sediment testing. 2. Interview with the technical supervisor #2 on January 4, 2019 at 12:00 PM confirmed the laboratory failed to include normal values for urine sediment testing in the procedure manual.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the hematology area and interview with technical supervisor #2, the laboratory failed to identify the contents and document the preparation and expiration dates of the reagents used in staining white blood cell (WBC) differentials. Findings: 1. Observation of the hematology area showed 3 unlabeled containers with no preparation or expiration dates. 2. Interview with technical supervisor #2 on January 4, 2019 at 12:00 PM confirmed the laboratory failed to identify the WBC staining material and include preparation and expiration dates.
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 the lack of documentation and interview with the technical supervisor #2, the laboratory failed to define a function check protocol to verify the accuracy of the timer and speed mechanisms on 2 of 2 laboratory centrifuges. Findings: 1. No documentation was found to show the laboratory defined a function check protocol to verify the accuracy of the timer and speed mechanisms on the Horizon mini E centrifuge used for chemistry and coagulation testing and the Clay Adams compact II used for urine microscopic testing. 2. Interview with technical supervisor #2 on January 4, 2019 at 11:30 AM confirmed, the laboratory failed to verify the accuracy of time and speed on the laboratory centrifuges.
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 review of quality control (QC) procedures, QC patient logs for December 2018 and interview with the technical supervisor #2, the laboratory failed to perform a positive and negative control each day of testing for moderately complex mononucleosis kit testing. Findings: 1. Review of QC procedures for mononucleosis kit testing showed the laboratory allowed usage of serum or plasma for mononucleosis. This changed the kit from waived complexity to moderate complexity. The policy showed "run a negative and positive control for any patient requesting for mono test. QC is good for 24 hours only." 2. Review of the QC patient logs for December 20 l 8 revealed the laboratory failed to perform a positive and negative external control for the 17th and the 19th of December 20 I 8. 3. Interview with the technical supervisor #2 on January 4, 2019 at 11:30 confirmed , the laboratory did not test a positive and negative control each day of testing.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based upon review of quality control(QC) logs and interview with the technical supervisor #2, the laboratory failed to run a control sample at least once every eight hours of patient testing of blood gas analytes. Findings: 1. Review of the QC logs showed the laboratory failed to perform a QC sample every 8 hours of patient testing. 2. Interview with the technical supervisor #2 on January 4, 2019 at 11:30 AM confirmed the laboratory failed to perform at least one control sample every 8 hours of patient testing.

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 the triage analyzer and the Beckman Coulter Access 2 chemistry analyzer for CKMB, myoglobin and troponin testing comparisons and interview with the technical supervisor #2, the laboratory failed to evaluate the relationship between the primary and backup chemistry analyzers twice a year. Findings: 1. Review of the Beckman Coulter Access 2 analyzer and the Triage analyzers showed the Access 2 was the primary and the Triage was the backup. The laboratory failed to define and evaluate the relationship between the two analyzers for the analytes: CKMB, myoglobin and troponin. 2. Interview with the technical supervisor #2 on January 4, 2019 at 11:30 AM confirmed the laboratory failed to evaluate the relationship between the two chemistry analyzers twice a year.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of approved reference ranges in the laboratory procedure manual and interview with the technical supervisor #2, the laboratory director failed to ensure the test report included pertinent normal ranges as determined by the laboratory. Three of the eighteen chemistry parameters and eighteen of eighteen complete blood cell (CBC) parameters listed on the laboratory information system (LIS) report differed from those in the approved procedure manual. Findings: 1. Review of the patient report from the LIS system revealed three of the eighteen chemistry parameters ranges did not correctly match those reference ranges in the procedure manual. LIS patient report Procedure manual Sodium 140- l 48 mmolJL 136-145 mmol/L Total bilirubin 0.00-1.00 mg/dL 0.1- l.3 mg/dL ALT l - 18 D/L 30-65 IU/L 2. Review of the CBC patient report from the LIS system revealed eighteen of eighteen parameters did not correctly match those reference ranges in the procedure manual. 3. Interview with the technical supervisor #2 on January 4, 2019 at 12:00 PM confirmed the laboratory director failed to ensure correct reference ranges approved in the procedure manual were included on the LIS patient report.