Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0675107	11/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Washington County Hospital	304 East 3rd Street, Washington, 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
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 hematology and urinalysis procedure manuals and interview with the technical supervisor #1, the laboratory failed to include reference intervals (normal values). Findings: 1. Review of the hematology procedure manual revealed a lack of normal values for complete blood cell(CBC) manual differential counts. 2. Review of the urinalysis procedure manual revealed a lack of normal values for urinalysis microscopic exams. 3. Interview with technical supervisor #1 on November 12, 2018 at 11:00 AM confirmed the laboratory failed to include normal values for manual differential counts and urine microscopic exams in the procedure manual.

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 observation of one Finnpipette and interview with technical supervisor #1, the laboratory failed to define and perform a function check protocol to verify the accuracy of the pipette. Findings: 1. Observation of one Finnpipette showed no function check performed. 2. Interview with the technical supervisor #1 on November 12, 2018 at 11:00 AM confirmed the laboratory failed to define and perform a function check to verify accuracy of one Finnpipette.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of verification procedures for the Sysmex XN 350 for complete blood cell counts(CBC) and interview with technical supervisor #1, the laboratory director failed to approve verification procedures. 1. Review of the verification procedures for the Sysmex XN 350 for CBC showed the analyzer was put into use on October 1, 2018. The laboratory director failed to verify the performance specifications. 2. Interview with the technical supervisor #1 on November 12, 2018 at 11:00 AM confirmed the laboratory director failed to ensure the verification procedures were adequate.