Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451118	09/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Medicine Lodge Memorial Hospital	710 North Walnut, Medicine Lodge, 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 procedure manual and interview, the laboratory failed to include reference ranges for routine chemistry, hematology, coagulation and urine microscopic analysis in the procedure manual. Findings: 1. Review of the routine chemistry procedure for arterial blood gas did not include reference ranges for pH, pCO2, and pO2. 2. Review of the hematology procedure did not include reference ranges for white blood count (WBC), red blood count (RBC), hematocrit. hemaglobin, platelets, and WBC diff. 3. Review of the coagulation procedure did not include reference ranges for prothrombin time, INR, and partial prothrombin time. 4. Review

	of the urinalysis procedure did not include reference ranges for urine microscopic analysis. 5. Interview with the General Supervisor (GS) on September 17, 2020 at 2: 20 p.m. confirmed, the laboratory failed to include reference ranges for routine chemistry, hematology, coagulation and urine microscopic analysis 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 an absence of thermometer function check records or certificates of accuracy and interview, the laboratory failed to define a function check protocol for the thermometers. Findings: 1. No documentation was available for function checks on 4 of 7 thermometers for a 2 year period. 2. No documentation was available for the certification of accuracy (NIST traceble) on 4 of 7 thermometers for a 2 year period. 2. Interview with the GS on 9/17/2020 at 2:15 p.m. confirmed, the laboratory failed to define a function check protocol for the thermometers.