Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453239	10/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Meade District Hospital	510 E Carthage Street, Meade, 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
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 confirmed during interview with the general supervisor (GS), the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current laboratory director did not approve, sign, and date the laboratory procedure/policy for: 34 of 34 procedures in Blood Bank and 15 of 15 procedures in Microbiology at time of survey. 2. Interview with the GS on October 12, 2021 at 11:30 a.m. confirmed, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use.
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 and hygrometer function check records or certificates of accuracy, protocols for thermometer and hygrometer function checks and interview with the general supervisor (GS), the laboratory failed to define and perform a function check protocol for 9 of 11 thermometers and 2 of 2 hygrometers. Findings: 1. No documentation was available for function checks on 9 of 11 thermometers and 2 of 2 hygrometers at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on 9 of 11 thermometers and 2 of 2 hygrometers at the time of survey. 3. Protocols for the function checks of thermometers and hygrometers were not made available at the time of survey. 4. Interview with the GS on October 12, 2021 at 12:10 p.m. confirmed, the laboratory failed to define and perform a function check protocol for 9 of 11 thermometers and 2 of 2 hygrometers.
D5459	CONTROL PROCEDURES CFR(s): 493.1256(d)(5)(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-- Each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon a review of quality control (QC) data in hematology and interview with general supervisor (GS), the laboratory failed to establish the criteria of acceptability, by documentation and procedure, for new lots of QC material before use on the hematology analyzer for 24 of 24 months: September 2019 to September 2021. Findings were: 1. During a review of QC data in hematology, the GS failed to provide testing data and evaluation for new lots of QC material for the Beckman DXH 600 prior to use. No evidence verifying acceptability of new lot of QC material was performed and reviewed before use in 24 of 24 months at time of survey. 2. Procedures for the Beckman DXH 600 in hematology which established the criteria for new lot of QC material were not made available at the time of survey. 3. Interview with the GS on October 12, 2021 at 1:15 p.m. confirmed, the laboratory failed to establish the criteria of acceptability, by documentation and procedure, for new lots of QC material before use on the hematology analyzer for 24 of 24 months: September 2019 to September 2021.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based upon review of QC and patient test records from the last 6 months, April 1, 2021 to October12, 2021, and interview with testing personnel #5 (TP#5) revealed the Technical Consultant (TC) failed to ensure acceptable levels of analytic performance

	were maintained for the OPTI arterial blood gas analyzer. Findings: 1. Examination of the OPTI arterial blood gas analyzer QC and patient test records revealed no review documentation by the TC for 6 months from April 1, 2021 to October 12, 2021. 2. Interview with TP#5 on October 12, 2021 at 2:45 p.m. confirmed, the TC failed to ensure acceptable levels of analytic performance were maintained for the OPTI arterial blood gas analyzer.