Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451118	06/26/2024
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of performance verification documentation for the lipase assay LIPL and extended range C-reactive protein assay RCRP on the Siemens Dimension EXL 200, and interview with the general supervisor GS, the laboratory failed to verify the lipase and C-reactive protein reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient results. Findings: 1. Review of the performance verification documentation of the lipase assay LIPL on the Siemens Dimension EXL 200 revealed no verification of normal values for the laboratory's patient population. Patient testing began on 11/17/23. 2. Lipase test volume from 11/17/23 to date of survey was 114 patient test results. 3. Review of the performance verification documentation of the extended range C-reactive protein assay RCRP on the Siemens Dimension EXL 200 revealed no verification of normal values for the laboratory's patient population. Patient testing began on 10/30/23. 4. Extended range C-reactive protein test volume from 10/30/23 to date of survey was 167 patient test results. 5. Interview with GS on 6/26/24 at 10:20 a.m. confirmed, the laboratory failed to verify the lipase and C-reactive protein reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient results.

D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation on the Quidel Triage Meter Pro for D-Dimer, lack of an individualized quality control plan (IQCP), patient test results, and interview with the GS, the laboratory failed to perform QC every eight hours of patient testing on the Quidel Triage Meter Pro for D-Dimer testing. Findings: 1. Review of the D-Dimer QC documents for the Quidel Triage Meter Pro test system revealed the laboratory failed to perform external QC every eight hours of patient testing. 2. No approved IQCP for the Quidel Triage Meter Pro test system was provided at the time of survey. 3. From 10/11/22 to 6/26/24, 168 patient results were reported without acceptable QC performed within eight hours of patient testing. 4. Interview with the GS on 6/26/24 at 12:30 p.m. confirmed the laboratory failed to perform QC every eight hours each day of patient testing on the Quidel Triage Meter Pro for D-Dimer testing.