Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	17D0648397	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Goodland Regional Medical Center	220 West 2nd St, Goodland, 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 review of performance verification documentation for the Sysmex XN-550 hematology analyzer, EPOC Blood Gas Analyzer and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population. Findings: 1. Review of the verification documentation of the Sysmex XN-550 hematology analyzer, S/N 20959, for the analytes: White Bloodcell Differential, Red Bloodcell Count, Hemoglobin, Hematocrit, White Bloodcell Count, and Platelet testing showed no verification of normal values at time of survey. Document listed patient testing began March 18, 2021. 2. Review of the verification documentation of the Siemens EPOC Blood Gas analyzer, S/N 28977, for the anyalytes: pH, pCO2, pO2, TCO2, Hematocrit, Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Lactic Acid, Urea Nitrogen, and Creatinine testing showed no verification of normal values at time of survey. Document listed patient testing began January 23, 2021. 3. Interview with technical supervisor #1 on September 21, 2021 at 2:30 p.m. confirmed, the laboratory failed to verify the reference intervals (normal values) for the Sysmex XN-550 and Siemens EPOC analyzers were appropriate for the laboratory's patient population.
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 chemistry Siemens Dimension EXL 200, Siemens EPOC procedures, lack of comparison records and interview, the laboratory failed to evaluate and define the relationship between test results using different methodologies and instruments. Findings include: 1. Review of chemistry analytes Sodium, Potassium, Chloride, Lactic Acid, Carbon Dioxide, Urea Nitrogen, Creatinine and Glucose showed they are performed on the Siemens Dimension EXL 200 S/N DE270815 and the Siemens EPOC S/N 28977. No procedure was available on how to evaluate and define the relationship between the chemistry test results. 2. No comparison testing records from January 23, 2021 to September 21, 2021 were made available at the time of survey. 3. Interview with the technical supervisor #1 on September 21, 2021 at 2:30 PM confirmed the laboratory failed to evaluate and define the relationship between the Siemens Dimension EXL 200 and Siemens EPOC test results for Sodium, Potassium, Chloride, Lactic Acid, Carbon Dioxide, Urea Nitrogen, Creatinine, and Glucose.