Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452770	06/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Edwards County Medical Center	620 West 8th Street, Kinsley, 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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on a lack of policies, procedures, specimen rejection logs, test request review documentation and interview, the laboratory failed to have written policies, procedures, and quality assurance (QA) documentation available for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic sytem. Findings: 1. A request was made to review the preanalytical policies and procedures. None were made availiable at the time of survey. 2. A request was made to review the specimen rejection log and test request review for QA documentation. None were made availiable at the time of survey. 3. Interview with the general supervisor (GS) 6/8/22 at 11:55 a.m. confirmed, the laboratory failed to have written policies, procedures, and QA documentation available for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic sytem.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, test complexity, procedure manual, quality control (QC) records and patient test results from 1/1/21 to the date of survey, and interview, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations for 42 of 47 patient results reported. Findings: 1. Review of the OPTI CCA TS Analyzer Operator's Manual revealed "OPTI Medical Systems recommends that QC solutions be run, as a minimum, with each new lot number of cassettes and at monthly intervals thereafter." 2. The OPTI CCA TS Analyzer can conduct basic testing of hydrogen ion concentration (pH), carbon dioxide partial pressure (PCO2), oxygen partial pressure (PO2), sodium (Na+), potassium (K+), ionized calcium (Ca++), chloride (Cl-), glucose (Glu), blood urea nitrogen (BUN), lactate (Lac), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO2) which are categorized as moderate complexity tests and require quality control at least once a day of patient testing with two control materials of different concentrations per 493. 1256. 3. Review of the laboratory's procedure "OPTI CCA TS Analyzer" revealed under "Quality Control Recommendations:" item 2. "Run one level of liquid control every day of patient testing. 4. Review of QC logs revealed that less than two controls of different concentrations were performed on 35 of 39 patient testing days for 42 of 47 patients. 5. Interview with the GS on 6/8/22 at 11:00 a.m. confirmed, the laboratory failed to perform QC at least once each day of patient testing for quantitative procedures, to include two control materials of different concentrations for 42 of 47 patient results reported from 1/1/21 to 6/8/22.