Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2104335	11/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Commonspirit Emergency And Urgent Care- Golden	760 Warner Dr, Golden, CO	

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 the lack of a written Quality Control Plan (QCP) and staff interview, the laboratory failed to establish written QCP within the Individualized Quality Control Plan (IQCP) to monitor, assess, and take corrective action as needed for the preanalytic laboratory system. Findings include: a. The technical consultant was unable to provide the surveyor with a written QCP. b. The technical consultant confirmed the laboratory had not written policies to evaluate preanalytic quality issues in the laboratory
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 review of the procedure manual and staff confirmation, the laboratory director failed to review, sign and date the approval of the Individualized Quality Control Plan (IQCP).
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 lack of verification records and staff interview, the laboratory failed to verify before initial patient use in June 2020 the manufacturer's stated performance specifications for the precision, accuracy and reportable range for sodium, chloride, potassium, calcium, glucose, lactate, blood gases (pH, PCO2, PO2), and creatinine on the Siemens EPOC analyzer . The technical consultant confirmed that the manufacturer's performance specifications had not been verified for this test system before reporting patient results.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to define in their Quality Control Plan (QCP) the number, type, and frequency of quality control (QC) materials to be tested for the Siemens EPOC analyzer when implementing an Individualized Quality Control Plan (IQCP). Findings include: a. The laboratory tests Sodium, Chloride, Potassium, Calcium, glucose, lactate, blood gases (pH, PCO2, PO2), and creatinine on the Siemens EPOC analyzer. b. Federal CLIA regulation requires external QC materials to be tested either each day of patient testing or according to the frequency supported by the documentation in a laboratory's Individualized Quality Control Plan (IQCP). c. The laboratory implemented an IQCP for the Siemens EPOC analyzer in 2020. d. The laboratory failed to provide documentation for the QCP. e. The laboratory's QCP was incomplete and did not describe the practices, resources, and procedures to control the quality of the test process for the Siemens EPOC analyzer, nor did it describe the number, type, or frequency of controls to be tested on the analyzer. f. Records showed two levels of QC materials were tested each month on the Siemens EPOC analyzer. g. Staff confirmed the QCP did not specify the number, type, and frequency of QC materials to be tested for the Siemens EPOC analyzer.