

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0956274	(X3) Date Survey Completed 01/22/2021
Name of Provider or Supplier Community Surgery Center East	Street Address, City, State 5445 East 16th Street, Indianapolis, IN	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document two different levels of quality control concentrations every day of patient testing, and no IQCP (Individualized Quality Control Plan) has been implemented for nine of nine analytes tested [Sodium (NA); Potassium (K); Chloride (Cl); Ionized Calcium (iCa); Glucose (Glu); Blood Urea Nitrogen (BUN/Urea); Creatinine (Crea); Hematocrit (Hct); and Total Carbon Dioxide (TCO2)], and seven of seven patient reports reviewed. Findings include: 1) Review of the "ENCLOSURE I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," indicated the laboratory had Na; K; Cl; iCa; Glu; BUN/Urea; Crea; Hct; and TCO2 listed as testing analytes. 2) The following patients were tested for Na; K; Cl; iCa; Glu; BUN/Urea; Crea; Hct; and TCO2, and two levels of external quality control were not performed each day of testing: P = patient Test = Abbott i-Stat Chem8+ P# Specimen Collection/Process Date a) P#2.....09/15/20 b) P#3.....10/01/20 c) P#4.....10/14/20 d) P#6.....11/25/20 e) P#7.....12/01/20 f) P#8.....12/18/20 g) P#10.....01/18/21 3) In interview on 01/22/21 at 2:00 pm, SP-1 confirmed two levels of quality control (QC) were not performed every day on testing analytes Na; K; Cl; iCa; Glu; BUN/Urea; Crea; Hct; TCO2; and there was no IQCP implemented. 4) Total annual test volume for = Na; K; Cl; iCa; Glu; BUN /Urea; Crea; Hct; and TCO2 = 29,700.</p>