Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2058861	01/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
St Joseph's Candler Urgent Care Center Bluffton	3 Progressive Street, Bluffton, SC	

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
D0000	A Recertification Survey was initiated on 01/08/2024 and concluded on 01/08/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of laboratory policy, documentation review, and interview, the laboratory failed to ensure proficiency testing (PT) was rotated among testing personnel (TP) for three of seven PT events reviewed for years 2021, 2022 and 2023. Findings included: Review of laboratory policy titled "Quality Assessment Program" dated 01/01/2023, "Proficiency Testing *PT samples are tested , to the extent possible, exactly like patient specimens, i.e., the same number of times and using the same personnel and methods as for patient testing. A review of PT records revealed TP #5 performed hematology and chemistry 2023 Events #1, #2, and #3. During an interview on 01/08/2024 at 12:30 PM, TP #5 acknowledged the laboratory failed to ensure PT sample testing was rotated among all TP.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on a review of laboratory policy, documentation review, and interview, the laboratory failed to ensure chemistry proficiency testing (PT) was conducted in the same manner as patient samples for four of six PT events reviewed for 2022, and 2023. Findings included: Review of facility policy titled "Quality Assessment Program," dated 01/01/2023, revealed, "Proficiency Testing *PT sampled are tested, to extent possible, exactly like patient specimens, i.e., the same number of times and using the same personnel and methods as for patient testing." A review of chemistry PT records revealed testing personnel tested chemistry PT twice. PT samples numbers 6 and 7 tested 05/23/2023, and 11 and 12 tested 09/18/2023 were run in duplicate. Testing was performed using i-STAT CHEM8+ cartridges which included Sodium (Na), Potassium (K), Chloride (Cl), Ionized Calcium (iCa), Total Carbon Dioxcide (TCO2), Glucose (Glu), Blood Urea Nitrogen (BUN), Creatinine (Crea), Hematocrit (Hct), Hemoglobin (Hb*), and Anion Gap (AnGap). None of the analyte results were documented as out of range. i-STAT CHEM8+ specimen ID:6 Na 144 mmol/L K 6.1 mmol/L Cl 111 mmol/L iCA 0.77 mmol/L TCO2 13 mmol/L Glu 86 mg/dL BUN 22 mg/dL Crea 1.1 mg/dL Hct 25 %PCV Hb* 8.5g/dL AnGap 27 mmol/L testing performed 9:23AM 22MAY23 i-STAT CHEM8+ specimen ID:6 Na 140 mmol/L K 3.8 mmol/L Cl 88 mmol/L iCa 2.12 mmol/L TCO2 26 mmol/L Glu 147 mg/dL BUN 63 mg/dL Crea 6.2 mg/dL Hct 25 %PCV Hb* 8.5 g/dL AnGap 31 mmol/L testing performed 11:05AM 23MAY22 TP-5 confirmed duplicate testing of PT specimens ran on May 22, 2023. i-STAT CHEM8+ specimen ID:7 Na 145 mmol/L K 4.2 mmol /L Cl 83 mmol/L iCa 1.09 mmol/L TCO2 22 mmol/L Glu 130 mg/dL BUN 37 mg/dL Crea 1.6 mg/dL Hct 35 %PCV Hb* 11.9 g/dL AnGap 45 mmol/L testing performed 9: 28AM 22MAY23 i-STAT CHEM8+ specimen ID:7 Na 145 mmol/L K 6.1 mmol/L Cl 110 mmol/L iCa 0.82 mmol/L TCO2 13 mmol/L Glu 85 mg/dL BUN 22 mg/dL Crea 1.1 mg/dL Hct 24 %PCV Hb* 8.2 g/dL AnGap 29 mmol/L testing performed 11: 10AM 23MAY22 TP-5 confirmed duplicate testing of PT specimens ran on May 22, 2023. i-STAT CHEM8+ specimen ID:11 Na 146 mmol/L K 4.2 mmol/L Cl 84 mmol /L iCa 1.09 mmol/L TCO2 19 mmol/L Glu 128 mg/dL BUN 38 mg/dL Crea 1.6 mg /dL Hct 34 %PCV Hb* 11.6 g/dL AnGap 48 mmol/L testing performed: 10:33AM 18SEP23 i-STAT CHEM8+ specimen ID:11 Na 125 mmol/L K 2.8 mmol/L Cl 76 mmol/L iCa 2.04 mmol TCO2 24 mmol/L3 Glu 180 mg/dL BUN 68 mg/dL Crea 4.2 mg/dL Hct 20 %PCV Hb* 6.8 g/dL AnGap 30 mmol/L testing performed 10:45AM 15SEP22 TP-5 confirmed duplicate testing of PT specimens ran on September 18, 2023. i-STAT CHEM8+ specimen ID:12 Na 125 mmol/L K 2.8 mmol/L Cl 75 mmol /L iCa 2.03 mmol/L TCO2 24 mmol/L Glu 176 mg/dL BUN 71 mg/dL Crea 3.8 mg /dL Hct 20 %PCV Hb* 6.8 g/dL AnGap 30 mmol/L testing performed 10:38AM 18SEP23 i-STAT CHEM8+ specimen ID:12 Na 145 mmol/L K 4.2 mmol/L Cl 84 mmol/L iCa 1.07 mmol/L TCO2 20 mmol/L Glu 133 mg/dL BUN 36 mg/dL Crea 1.7 mg/dL Hct 34 %PCV Hb* 11.6 g/dL AnGap 45 mmol/L testing performed 10:45AM 15SEP22 TP-5 confirmed duplicate testing of PT specimens ran on September 18, 2023. During an interview on 01/08/2024 at 12:30 PM, TP #5 confirmed chemistry PT was tested twice, and normal patient samples were tested once. TP #5 acknowledged the laboratory failed to ensure chemistry PT was tested in the same manner as patient samples.