

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2064789	<b>(X3) Date Survey Completed</b>  03/23/2021
<b>Name of Provider or Supplier</b>  St Joseph's Candler Urgent Care Centers	<b>Street Address, City, State</b>  107 Canal Street, Pooler, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on March 23, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE), Proficiency Testing (PT) provider, the laboratory failed to enroll in PT for the first event in Hematology, and Chemistry for the year 2020. Findings: 1. Review of the MLE, PT documents for the year 2020, for the Specialty of Hematology and Chemistry, there was no documents for the First events of Chemistry and Hematology. 2. Interview with staff #1, and the Corporate Office Manager, on March 23, 2021 at approximately 4pm in the Manager's office, confirmed that they did not participate in the first event of 2020 for Hematology and Chemistry PT testing. It was also acknowledged that this was due to failure to renew the subscription of the 2020 PT testing with MLE. After this error was discovered, the PT material was ordered immediately. A score of 100 % for both second and third events for Hematology and Chemistry was received on the MLE evaluation report.</p>

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) the year 2020, for the Speciality of Hematology and Chemistry, the Laboratory Director failed to ensure that the laboratory was enrolled in a HHS approved proficiency testing program for the testing performed. Findings: 1. Review of the MLE, PT documents for the year 2020, for the Specialties of Hematology and Chemistry, there was no documents for the First events of Chemistry and Hematology. 2. Interview with staff #1, and the Corporate Office Manager, on March 23, 2021 at approximately 4pm in the Manager's office, confirmed that they did not participate in the first event of 2020 for Hematology and Chemistry PT testing. It was also acknowledged that this was due to not renewing the subscription for the 2020 PT testing with MLE. After this error was discovered, the PT material was ordered immediately. A score of 100 % for both second and third events for Hematology and Chemistry was received on the MLE evaluation report.