

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2042589	(X3) Date Survey Completed 10/08/2019
Name of Provider or Supplier St Joseph's Candler Imaging Center-Bluffton	Street Address, City, State 10-A Oak Forest Road, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 10/08/2019, based on laboratory procedure manual review, laboratory refrigerator temperature record review, and staff interview, it was determined that the laboratory failed to maintain acceptable refrigerator temperatures between for 24 of 30 days reviewed in January 2019. Findings include: 1. The laboratory procedure manual had a required refrigerator temperature range between 2 and 8 degrees Celsius. 2. Review of the laboratory's temperature records revealed that refrigerator temperatures were recorded below 2 degrees Celsius for a total of 24 of 30 days reviewed in January 2019. There was no corrective action for the out of range temperatures during this time period available for review. 3. Testing personnel confirmed during an onsite interview at 3:00 pm that the laboratory had failed to maintain proper refrigerator temperatures. .</p>
D5777	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c)</p> <p>(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of</p>

patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

During an onsite recertification survey on 10/08/2019, based on the lack of documentation and testing personnel interview, the laboratory failed to develop and follow a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: patient age, sex, diagnosis or pertinent clinical data, distribution of patient test results, and relationship with other test parameters for 2 of 2 years reviewed (2017 and 2018). Findings include: 1. The laboratory's system to identify and assess patient test results that appear inconsistent with the following relevant criteria; patient age, sex, diagnosis or pertinent clinical data, distribution of patient test results, and relationship with other test parameters was unavailable for review on the day of the survey. Documentation of any routine review was unavailable on the day of the survey. 2. Testing personnel confirmed during an onsite interview on 10/08/2019 at 3:00pm that the laboratory had failed to ensure routine test result comparisons were performed as required.