

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2106529	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier St Joseph's Candler Urgent Care Centers Rincon	Street Address, City, State 5621 Ga Highway 21 S, Rincon, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 12, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and staff interview, the laboratory director failed to review QC records for testing performed in the speciality of hematology in 2016, 2017 & 2018 on the Medonic M series analyzer. Findings include: 1. Review of 2016, 2017 & 2018 QC records including Levy Jennings charts, monthly control printouts and peer review reports for testing performed on the Medonic M series hematology analyzer revealed no documentation of review by the laboratory director. 2. Interview with the office manager on June 12, 2018 in the manager's office confirmed that QC is not reviewed by the laboratory director and the only review is of daily QC results performed by testing personnel who are not trained to interpret the reports listed above.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p>

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's testing personnel's competency assessment checklist as well as interview with the office manager, the technical consultant failed to ensure the competency assessment policy and procedure for testing performed in the speciality of hematology met the 6 required criteria and failed to perform the assessment on 5 of 5 testing personnel.. Findings include: 1. Review of the laboratory competency assessment checklist revealed it does not include: A. Direct observation of patient test performance, including patient preparation, specimen handling, processing and testing B. Direct observation of performance of instrument maintenance and function checks. C. Assessment of test performance using previously analyzed samples. 2. Competency assessment for 5 of 5 testing personnel is signed by the office manager instead of the technical consultant who is the only person qualified to assess competency. 3. Interview with the office manager on June 12, 2018 in the manager's office at 1:15 pm confirmed competency assessment is not performed by the technical consultant and it does not include the three required criteria listed above.