

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0695191	(X3) Date Survey Completed 04/15/2019
Name of Provider or Supplier Candler Medical Oncology Practice	Street Address, City, State 5400 Sutlive Street, Savannah, 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 April 15, 2019. 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:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature and humidity logs the laboratory failed to take corrective action when the humidity of laboratory fell outside the acceptable range. Findings include: 1. Review of the laboratory's temperature and humidity logs revealed the humidity fell outside the acceptable range on the following: December 2017 4 of 20 days January 2018 8 of 20 days November 2018 6 of 19 days December 2018 14 of 20 days January 2019 10 of 22 days February 2019 5 of 21 days March 2019 9 of 21 days 2. Review of laboratory records revealed no documentation of corrective action for any of the unacceptable values. 3. Interview with testing personnel # 1 (see CMS 209) on April 15, 2019 at 2:30 pm in the office assigned to the surveyor confirmed corrective action was not taken on any of the days when the humidity fell outside the acceptable range.</p>

<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the laboratory director failed to document review of all three event's PT reports in 2018. Findings include: 1. Review of events 1, 2 and 3 API PT records for 2018 revealed no documentation showing the Laboratory director reviewed the results. 2. Interview with testing personnel # 1 (see CMS 209) on April 15, 2019 at 2:30 pm in the office assigned to the surveyor confirmed there is no documentation showing the laboratory director reviewed PT results in 2018.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and staff interview, the technical consultant failed to perform competency assessment on testing personnel. Findings include: 1. Review of 2017 and 2018 competency assessment records for 4 of 4 testing personnel listed on the CMS 209 form revealed competency assessment is performed by the nursing supervisor who is not qualified by CLIA regulations to perform the assessment. 2. Review of the CMS 209 form revealed the technical consultant is the only person qualified to perform competency assessment. 3. Interview with testing personnel # 1 (see CMS 209) on April 15, 2019 at 2:30 pm in the office assigned to the surveyor confirmed competency assessment is performed by the nursing supervisor and not the technical consultant.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at</p>

least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of testing personnel records, review of the Laboratory Personnel Report form (CMS 209) and staff interview, the laboratory director failed to ensure 2 of 4 testing personnel listed on the CMS 209 form had a minimum of a high school diploma or equivalent. Findings include: 1. Review of the CMS 209 revealed 4 employees listed as testing personnel (TP). 2. Review of testing personnel (TP) records revealed no documentation of a high school diploma or equivalent for 2 of 4 TP (TP # 3 & 4). 2. Interview with the nurse manager and testing personnel # 1 (see CMS 209) on April 15, 2019 at 2:30 pm in the office assigned to the surveyor confirmed documentation of education is not available for 2 of the 4 TP.