

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0695191	<b>(X3) Date Survey Completed</b>  04/27/2021
<b>Name of Provider or Supplier</b>  Candler Medical Oncology Practice	<b>Street Address, City, State</b>  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.		

<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 April 27, 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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records, CMS 209 form, and staff interview, the laboratory failed to rotate PT sample testing among all laboratory testing personnel (TP). Findings include: 1. Review of the CMS 209 personnel form reveals 2 TP are employed by the lab. 2. Review of the College of American Pathology (CAP) and American Proficiency Institute (API) PT records reveals Staff #2 (CMS 209 form) performed all PT samples in the API 2019 Event #3; CAP 2020 Events # 1, 2, &amp; 3; and CAP 2021 Event #1. 3. Interview at approximately 12:30 PM with staff #2 (CMS 209 form) on 4/27/21 in a provider's office, confirms she performed all aforementioned PT.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

This STANDARD is not met as evidenced by:  
Based on review of proficiency test (PT) records and staff interview, the laboratory director (LD) failed to attest PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the College of American Pathology (CAP) and American Proficiency Institute (API) PT records reveals the LD (CMS 209 form) failed to attest the PT samples were tested in the same manner as patient specimens in the API 2019 Event #3, CAP 2020 Events # 1, 2, & 3. 2. Interview at approximately 12:30 PM with staff #2 (CMS 209 form) on 4/27/21 in a provider's office, confirms the LD failed to attest on the aforementioned PT.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were reviewed upon receipt from the PT agency. Findings include: 1. Review of the College of American Pathology (CAP) and American Proficiency Institute (API) PT records for API 2019 event #3 and CAP 2021 event #1 reveals the LD failed to document review PT results upon receipt from the PT agency. 2. Interview at approximately 12:30 PM with staff #2 (CMS 209 form) on 4/27/21 in a provider's office, confirms the LD failed to document review the aforementioned PT.