

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1006560	<b>(X3) Date Survey Completed</b>  06/09/2020
<b>Name of Provider or Supplier</b>  Lake City Cancer Care Llc	<b>Street Address, City, State</b>  289 Sw Stonegate Terrace Ste 103, Lake City, FL	
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>	An announced CLIA recertification survey was conducted at Lake City Cancer Care, LLC on June 9, 2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<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 CMS 209- Laboratory Personnel Report, review of American Proficiency Institute ( API ) proficiency testing, and interview with the Laboratory Staff, the laboratory failed to have all testing personnel to rotate the proficiency testing for the specialty of Hematology for 2 of 2 years reviewed ( 2018-2020). Findings Included: Review of the CMS 209 (signed and dated by the Laboratory Director 06/09/20 ) had 11 testing personnel listed ( #2 - #12 ). Review of API proficiency testing for the specialty of Hematology found that Testing Person #9 was the only person who performed the proficiency testing in 2018 through 2020. Interview with the Laboratory Staff on 06/09/20 at 2:00 PM confirmed that Testing Person #9 was the only person performing proficiency testing even though Testing Person #2 - #12 all performed patient testing.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> 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</p>

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Staff, the Technical Consultant failed to perform the testing personnel competency assessments for 11 (#2--#12) out of 11 testing personnel for 2 of 2 years ( 2018-2020 ) reviewed.

Findings Included: Review of the personnel files revealed that Testing Person # 9 signed off on the competency evaluations for 10 Testing Personnel. Testing Person # 9 was signed off by Testing Person # 2. Testing Person # 9 does not meet the qualifications to perform the duties of the Technical Consultant . Testing Person # 2 was not delegated as the Technical Consultant. Interview on 06/09/20 at 2:00 PM with Laboratory Staff, confirmed that the Technical Consultant did not perform or sign the testing personnel competency evaluations.