

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0022561	<b>(X3) Date Survey Completed</b>  04/04/2022
<b>Name of Provider or Supplier</b>  Reception And Medical Center Clinical Laboratory	<b>Street Address, City, State</b>  7765 S County Road 231, Lake Butler, 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 recertification survey was conducted on 4/4/22 at Reception and Medical Center, a clinical laboratory in Lake Butler, Florida. Reception and Medical Center is in not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. .
<b>D5213</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing results and staff interview, the laboratory failed to verify the accuracy of analytes that did not receive a grade for one out of three testing events in 2021. The findings include: Review of CAP proficiency testing results showed the laboratory did not investigate the exception reason code 11 that appeared as a score for the evaluation of the results submitted for the following event: AQI-C 2021. The interview with Testing Person I on 4/4/2022 at 11:00am confirmed the laboratory failed to follow CAP guidance and perform a self-evaluation after receiving an exception code of 11. .</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 test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Consultant (Laboratory Director) failed evaluate the competency of testing personnel listed on the Laboratory's Personnel Report for 8 of 11 personnel (A, C, D, E, G, I, J, K) for 2021. The findings include: Review of personnel competency assessments showed Testing Person A, C, D, E, G, I, J, and K were assessed for competency in 2020 and 2022. There was no documentation showing competency was assessed in 2021. The interview with Testing Person I on 4/4/2022 at 11:00am confirmed the personnel competency assessments for 2021 were missing.