

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2169391	<b>(X3) Date Survey Completed</b>  07/14/2020
<b>Name of Provider or Supplier</b>  Lakewood Asc, Llc	<b>Street Address, City, State</b>  5571 E Sr 44 Suite 501, Wildwood, 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 initial survey was conducted at Lakewood ASC on 07/14/20. 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>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency test records and interview with the Testing Personnel, the laboratory failed to test Hematology proficiency samples for Activated Clotting Time (ACT) the same number of times that patient test samples were tested for one event (2020 1st event) of one event reviewed. Findings included: Review of the laboratory's "Proficiency Testing" procedure revealed "General Guidelines" to include: "Analyze PT specimens according to patient protocols at all times throughout the process. For example, if a patient specimen is routinely tested only once, then do the same with the PT specimens: test only one time..." Review of the laboratory's API proficiency testing Attestation Statement for the ACT 2020 1st Event revealed signatures of 4 Testing Personnel for a testing event consisting of only two samples. Testing Personnel #A and #D had attested that on 03/19/20 they had tested specimen 1AC - 01 and Testing Personnel #B and #F had attested that on 03/19/20 that they had tested specimen 1AC -02. Interview on 07/14/20 at 12:30 PM with Testing Personnel #A and #B revealed that they thought that each testing personnel could test each sample one time and not that each sample was to be tested only once like the patients. Testing Personnel #A and #B also stated that Testing Personnel #B and #F had tested the proficiency testing samples after proficiency testing results had been submitted but not after the proficiency testing postmark due date.</p>