

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0919316	<b>(X3) Date Survey Completed</b>  03/06/2018
<b>Name of Provider or Supplier</b>  Island Coast Pediatrics Pa	<b>Street Address, City, State</b>  632 Del Prado Blvd N, Ste 300, Cape Coral, 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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not calibrate the cell counter every six months. Findings include: Review of the operator's manual and hematology quality control records and maintenance records for the past two years on 03/06/18 revealed that the laboratory calibrated the cell counter on 08/23 /16 and the next calibration was on 05/08/17. The operator's manual indicated that the cell counter should be calibrated at least every six months. During an interview with the office supervisor at 11:40 a.m. on 03/06/18, she confirmed the there was no documentation to indicate that the cell counter had been calibrated between August, 2016 and May, 2017.</p>