

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0679478	<b>(X3) Date Survey Completed</b>  08/30/2018
<b>Name of Provider or Supplier</b>  Island Coast Pediatrics Pa	<b>Street Address, City, State</b>  13650 Metropolis Ave Ste 101, Fort Myers, 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>D2122</b>	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory received an unsatisfactory score in hematology for the second proficiency testing event of 2018. Findings include: Review of proficiency testing records for 2017 and 2018 on 08/30/18 revealed that the laboratory received scores of 0% for platelets, white blood cell count (WBC), and erythrocyte count (RBC) resulting in an overall score of 46%. During an interview with the office supervisor at 10:15 a.m. on 08/30 /18, she confirmed that they had an unsatisfactory score on that proficiency test.</p>
<b>D5437</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION 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>

This STANDARD is not met as evidenced by:  
Based on record review and interview with laboratory personnel, the hematology analyzer was not calibrated every six months. Findings include: Review of the cell counter calibration records for the past two years on 08/30/18 revealed that the instrument was calibrated on 02/11/17 and not again until 12/06/17. The laboratory policy was to calibrate the cell counter at least every six months. During an interview with the office supervisor at 10:45 a.m. on 08/30/18, she confirmed that there was a lapse in calibrations in 2017.

**D6019**

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on record review and interview with laboratory personnel, the director did not ensure that corrective action was done when proficiency testing results were unsatisfactory. Findings include: Review of proficiency testing records for 2017 and 2018 on 08/30/18 revealed that the laboratory received a score of 46% for hematology, but there was no documentation to indicate that any corrective action had been taken. The proficiency testing scores for platelets, white blood cells (WBC), and erythrocytes (RBC) were 0% resulting in an overall unsatisfactory score of 46% for hematology. During an interview at 10:15 a.m. on 08/30/18, the office supervisor confirmed that there was no documentation of any corrective action having been taken.