

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0907332	(X3) Date Survey Completed 05/01/2019
Name of Provider or Supplier Island Coast Pediatrics Pa	Street Address, City, State 9911 Corkscrew Rd Ste 101, Estero, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not receive at least 80 percent on two proficiency testing events over the past two years. Findings include: The surveyor reviewed the past two years of proficiency testing results on 05/01/2019 and found the following unsatisfactory results. 1. For the second testing event of 2017, the laboratory received an unsatisfactory score of 60 percent for platelets. 2. For the third testing event of 2018, the laboratory received an unsatisfactory score of 60 percent for cell identification or white blood cell (WBC) differential. During an intrview with the office supervisor at 10:40 a.m on 05/01/2019, she confirmed that they had received unsatisfactory scores for those two events.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, there was no</p>

documentation to indicate that the laboratory director ensured that corrective action was taken when proficiency testing results were unsatisfactory. Findings include: The surveyor reviewed all proficiency testing records for the past two years on 05/01/2019, and there was no documented corrective action when the laboratory received unsatisfactory scores of 60% for platelets for the second testing event of 2017 and 60% for cell identification/ white blood cell (WBC) differential for the third testing event of 2018. During an interview with the office supervisor at 10:40 a.m. on 05/01/2019, she confirmed that they had not documented corrective action for the unsatisfactory events.