

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0907332	<b>(X3) Date Survey Completed</b>  07/30/2025
<b>Name of Provider or Supplier</b>  Island Coast Pediatrics Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Island Coast Pediatrics PA on 07/29/2025 - 07/30/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2016 493.803 Condition: Successful Participation D6063 493.1403 Condition: Moderate Complexity Lab Director.
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory did not have successful</p>

	<p>performance in proficiency testing for three (2024 2nd event and 2025 1st and 2nd events) of four events (2024 2nd and 3rd events and 2025 1st and 2nd events) in the specialty of Hematology. Refer to D2130.</p>
<p><b>D2123</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p> <p>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in one (test event 2, 2024) of six test events (test events #3, 2023, #1 - #3, 2024, #1 - #2, 2025) reviewed resulting in a score of 0, unsatisfactory performance, for the specialty of Hematology. Findings included: 1. Review of the laboratory's College of American Pathologists (CAP) evaluation records revealed a score of 0%, unsatisfactory performance, for test event #2 in 2024 for the specialty of Hematology. 2. Testing Personnel A and the Laboratory Director confirmed on 7/29/25 at 1:45 p.m. the above.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have successful performance in proficiency testing for three (2024 2nd event and 2025 1st and 2nd events) of four events (2024 2nd and 3rd events and 2025 1st and 2nd events) in the specialty of Hematology. Findings included: 1. Review of the laboratory's College of American Pathologists (CAP) evaluation records for 2024 2nd event and 2025 1st and 2nd events documented the lab failed to successfully participate in the specialty of Hematology for the analyte of Hematocrit (HCT) non-waived. 2024 2nd event -HCT non-waived 0% 2025 1st event-HCT non-waived 40% 2025 2nd event-HCT non-waived 20% 2. Testing Personnel A and the Laboratory Director confirmed on 7/29 /25 at 1:45 p.m., the above unsuccessful results for the analyte of Hematocrit (HCT) non-waived for the 2024 2nd event and 2025 1st and 2nd CAP proficiency events.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p>

This CONDITION is not met as evidenced by:  
Based on record review and interview, the Laboratory Director failed to ensure the laboratory maintained successful proficiency performance for three (2024 2nd event and 2025 1st and 2nd events) of four events (2024 2nd and 3rd events and 2025 1st and 2nd events) in the specialty of Hematology (refer to D6016) and failed to complete a competency on Technical Consultant #B for one (2023) of two years (2023, 2024) reviewed and failed to complete competencies for three (#A, #C, #D) of six (#A - #F) testing personnel (TP) selected for review for 2023 - 2024. (See D6030).

**D6016**

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

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on record review and interview, the Laboratory Director failed to ensure the laboratory maintained successful proficiency performance for three (2024 2nd event and 2025 1st and 2nd events) of four events (2024 2nd and 3rd events and 2025 1st and 2nd events) in the specialty of Hematology. Refer to D2130.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on record review and interview, the Laboratory Director failed to complete a competency on Technical Consultant #B for one (2023) of two years (2023, 2024) reviewed, and failed to complete competencies for three (#A, #C, #D) of six (#A - #F) testing personnel (TP) selected for review for 2023 - 2024. Findings included: 1. The Laboratory Policy & Procedure titled Proficiency/Laboratory Competency Testing Program with revision dates of 03/2/22, 04/24/24 and 01/31/25 was reviewed. The policy stated new employees would have two competencies completed in the first six months of employment and every employee would have a competency completed annually, observed and signed off by the Laboratory Director or designee. The policy also stated the Laboratory Director would observe the employees as part of their competency. The policy stated competency assessments would be completed on all staff. 2. Review of the CMS-209 Laboratory Personnel Report, signed and dated 07/28/2025 by the Laboratory Director, documented two Technical Consultants (TC). TC #A, who is also the Laboratory Director, and TC #B. The CMS-209, signed and dated by the Laboratory Director 07/14/2023 for the previous survey was reviewed. TC #B was listed on the form. 3. TC #B's competencies for 2023 and 2024 were reviewed. There was no competency assessment for 2023. 4. The CMS-209 Laboratory

Personnel Report, signed and dated 07/28/2025 by the Laboratory Director and the CMS-209, signed and dated by the Laboratory Director 07/14/2023 for the previous survey were reviewed. A comparison of testing personnel (TP) listed on the form revealed the laboratory currently had six TP (#A - #F), four (#A, #C, #D, #E) of which were new (not previously listed on the 209). 5. TP competencies were reviewed. 5a. TP #A had competency form dated 12/10/2023, 04/01/2024, 12/19/2024 and 06/25/2024. 5b. TP #C had competency forms dated 04/14/2024, 12/19/2024, and 06/25/2025. 5c. TP #D had competency forms dated 12/19/2024 and 06/25/2024. All forms were signed by the Office Manager and Laboratory Director however, it was unclear who was completing the competencies and performing observation of the TP. 6. An interview was conducted with TP #A, Clinic Department Manager on 07/29/2025 at 11:41 a.m. TP #A stated the Office Manager or Clinical Department Manager filled out the competency forms and conducted the observations then gave the forms to the Laboratory Director for signature. 7. An interview was conducted with the Laboratory Director on 07/29/2025 at 1:35 p.m. The Laboratory Director confirmed the above data.