Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0919316	04/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Island Coast Pediatrics Pa	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An on-site announced CLIA recertification survey was conducted at Island Coast Pediatrics on 04/10/2024 - 04/16/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain temperature logs for room temperatures for two out of two years (2022 - 2024). Findings Included: Review of the policy titled Quality Assurance Program (revised 4/22/22 and signed by the previous Clinical Department Manager) revealed under the subheading Quality Control: Room and Room Humidity are recorded daily every "AM [morning], NOON, and PM [anytime after 12:00 PM]" and saved for two years. Review of the temperature charts revealed the laboratory did not retain the electronic room temperature and humidity documentation from 04/15/2022 - 03/06/2024. On 04/10 /2024 at 12:00 PM, the Clinical Department Manager and the Human Resource Manager stated the information technology personnel could only retrieve room temperature and room humidity data 30 days from the date of survey.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on record review of College of American Pathologists (CAP) proficiency testing and interview with staff, who had been delegated to sign for proficiency testing results, the laboratory failed to document corrective actions for unsatisfactory and unsuccessful proficiency testing (PT) for hematology (hematocrit) for two (A and B Event 2023) out of five PT events reviewed (B and C Event 2022, and A, B, and C Events 2023) Findings included: A record review of the CAP hematology PT results revealed the Technical Consultant failed to document corrective action for unsuccessful PT for hematology (hematocrit) for the A Event for 2023 and the unsatisfactory hematology (hematocrit) B Event of 2023. Record review of the laboratory's "Unsatisfactory Proficiency Tests" policy (reviewed 3/2/22 but unsigned by the laboratory director) revealed: 2. When an unsatisfactory PT result is received, corrective action must take place immediately. 3. The first occurrence of unsuccessful PT Performance will be to undertake training of all personnel, obtain necessary technical assistance, and/or both pertaining to the incident. All training and/or technical assistance must be documented. 4. The Clinical Compliance Coordinator will be monitoring all PT results each quarter for all testing labs. Record review of the "Quality Assurance Program" policy (revised 4/22/22 and signed by the previous Clinical Department Manager) under the subheading "Proficiency Testing" revealed "PT failures are investigated and remedial action is taken and reviewed by the Lab Director or his designees." On 04/10/2024 at 11:35 AM, the previous Clinical Department Manager stated she must have overlooked addressing the unsuccessful and unsatisfactory proficiency testing events.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on interview and review of policies, the laboratory failed to have policies and procedures that were approved, signed, and dated by the Laboratory Director for two (2022 - 2024) out of two years (2022 - 2024) reviewed. Findings included: Review of the laboratory policies and procedures revealed the Laboratory Director had not approved, signed and dated the policies and procedures. On 04/10/2024 at 1:40 PM, the previous Clinical Department Manager stated the office never had the policies and procedures approved, signed, and dated by the Laboratory Director.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory failed to monitor hematology quality control (QC) over time for shifts and trends for two out of two years (2022-2024) reviewed. Findings Included: Record review of the laboratory's policy "Quality Assurance Program" revealed the Lab Director or designee reviews and signs all QC results during monthly purging prior to being saved in the control binder. Record review of QC records revealed that the laboratory did not have documentation that the hematology monthly purging records had been reviewed for shifts and trends by the Laboratory Director or designee. On 04/10/2024 at 12:50 PM, the Clinical Department Manager and Human Resource Manager confirmed monitoring of QC for shifts and trends was not being conducted.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the Laboratory Director failed to specify in writing the responsibilities and duties (job descriptions) of the laboratory director, clinical consultant, two technical consultants, and testing personnel. Findings included: The laboratory failed to provide written job descriptions for the laboratory director, clinical consultant, technical consultant, and testing personnel when the job descriptions were requested. Record review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 04/10/2024, revealed there was one laboratory director, one clinical consultant, two technical consultants (this included the laboratory director), and 6 testing personnel. On 04/10 /2024 at 2:30 PM, the Clinical Department Manager and Human Resource Manager confirmed there were no job descriptions.