Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0907332	05/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Island Coast Pediatrics Pa	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
D0000	An announced recertification survey was conducted on 5/11/21 at Island Coast Pediatrics Pa, a clinical laboratory in Estero, Florida. Island Coast Pediatrics Pa is not in compliance with the Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the Hematology instrument manual used by the laboratory, lack of documentation, and interview with the Clinical Department Manager, the laboratory failed to document the room temperature and humidity for two out of two years reviewed (2019-2021). The findings included: Review of the Hematology instrument manual revealed the test device required an instrument room temperature of 64 - 90 degrees Fahrenheit (18 - 32 degrees Celsius) and a maximum humidity of 80%. Review of the Quality Assurance revealed no policy for recording room temperature and humidity. Interview on 5/11/21 at 3:25 p.m., the Clinical Department Laboratory Manager stated that she did not know that the room temperature and humidity needed to be recorded. .
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of record review, and interview with the Clinical Department Manager, the laboratory failed to verify the quality control manufacturer's recommended range for the Hematology controls that were used on the hematology instrument for two out of two years (2019-2021). The findings included: Review of Hematology quality control records revealed the lack of quality controls records for verification of quality control manufacturer's recommended ranges for the new lot of Hematology controls for two out of two years (2019-2021). Interview on 5/11/21 at 2: 15 p.m., the Clinical Department Manager stated the laboratory did not know to verify the quality control manufacturer's recommended ranges for new lot of Hematology controls. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review, and interview with the Clinical Department Manager, the laboratory director failed to perform the quality assurance (QA) activity of reviewing quality control records for two out of two years (2019 - 2021). The findings included: Review of quality control records revealed that there was no quality assurance (Laboratory Director signature) documentation for two out of two years (2019 to 2021). Interview on 5/11/21 at 3:20 p.m., the Clinical Department Manager stated that she did not know that the Laboratory Director should review the quality control records. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(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 with Clinical Department Manager, the Laboratory Director failed to ensure that staff followed a written procedure that described the process for documenting the competency assessment of 5 (Consultants #H, #I, #J, #K, and #L) out of 5 Technical Consultants for two out of two years (2019-2021). The findings included: Record review of competency assessments revealed the Laboratory Director had not performed competency assessment on 5 (Consultants #H, #I, #J, #K, and #L) out of 5 Technical Consultant for two out of two years (2019-2021). Record review of the laboratory's procedure manual showed a Quality Assurance Program policy that included a section titled "Personnel" that stated "Personnel are evaluated during the first year of employment or when new methodologies are incorporated. Thereafter, evaluations are performed yearly." But the policy did not include how to determine the competency for the Technical Consultant. Interview on 5/13/21 at 3:30 p.m., the Clinical Department Manager stated the Technical Consultants did not perform testing and she did not know that the laboratory should have a procedure for determining the competency of the Technical Consultant. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review, and interview with the Clinical Department Manager, the Technical Consultant (who is also the Laboratory Director) failed to perform semi-annual competencies on 2 (Personnel #B, and #C) out of 3 newly hired Testing Personnel. The findings included: Review of employee files revealed that Testing Personnel #B had a hire date as of 10/3/19 and competency evaluations were conducted 1/29/20 and 1/2/21. Testing Personnel #C had a hire date of 12/3/19 and competency evaluations were conducted 2/03/20 and 1/1/2021. Interview on 5/11/21 at 2:00 p.m., the Clinical Department Manager confirmed that semi-annual competency evaluations had not been completed for Testing Personnel #B and #C.