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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0919316 | (X3) Date Survey Completed 04/14/2022 |
| Name of Provider or Supplier Island Coast Pediatrics Pa | Street Address, City, State 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 |
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| D0000 | An announced recertification survey was conducted on 4/14/22 at Island Coast Pediatrics Pa, a clinical laboratory in Cape Coral, Florida. Island Coast Pediatrics Pa was found NOT in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories. . |
| D5481 | <p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to have quality controls (QC) in acceptable range prior to reporting patient results for 1 of 31 days in March 2022. The findings include: Record review of the laboratory's QC records for March 2022 showed on 3/7/22, the low level control for the hematology test of Platelet was out of range at 48 (acceptable range was 52-103), the normal level control for the hematology test of Platelet was 174 (acceptable range was 185-255). The laboratory failed to document corrective action and performed/reported testing on 10 patients. During interview on 4/14/22 at 9:15am, testing person B confirmed the QC was out of range for the two control levels on 3/7/22 and verified that patient testing should not have been performed until QC was in range.</p> |