Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0273001	(X3) Date Survey Completed 01/19/2023
Name of Provider or Supplier Pediatric Associates	**Street Address, City, State** 475 Osceola St Ste 1100, Altamonte Springs, 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	A recertification survey was conducted on January 19, 2023. Pediatric Associates clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to include the units of measurement on the laboratory test results reports for three of three patients, (#1, #2, #3) tested for Bilirubin on the Unistat Bilirubinometer. Findings: Review of the package insert for the Bilirubin controls listed the units of measurement as mg/dL (milligrams /deciliter). Review of the laboratory test results reports showed the unit of measurement were not listed for three of three patients' reports (#1, #2, #3) tested for Bilirubin. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 01/16 /2023, the laboratory had an annual test volume for the specialty of routine chemistry of 150 tests. On 01/19/2023 at 2:45 PM, the Practice Manager stated the reports did not include units of measurement.
D5807	TEST REPORT

	CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to include the normal values on the laboratory test results reports for three of three patients (#1, #2, #3) tested for Bilirubin on the Unistat Bilirubinometer. Findings: Review of the laboratory test results reports showed the normal values were not listed for three of three patients' reports (#1, #2, #3) tested for Bilirubin. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 01/16/2023, the laboratory had an annual test volume for the specialty of routine chemistry of 150 tests. On 01/19/2023 at 2:45 PM, the Practice Manager stated the reports did not include the normal values.