Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0901350	09/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates - Skylake	1610 Ne Miami Gardens Dr, North Miami Beach, 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 September 5 to 12 of 2024. PEDIATRIC ASSOCIATES INC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain copies of the instrument test results and attestation records for Hematology proficiency events #1 and #2 for the year 2023. Findings included: 1-Review of the American Pathology Institute (API) Proficiency Testing records showed that the laboratory did not maintain a copy of the instruments test results from the Medonic Hematology analyzer and attestations for the 1st and 2nd event in 2023. 2- During interview on 09/05/2024 at 3:37 PM, the laboratory lead confirmed that the laboratory did not keep the records for these two events and a quality assessment was performed to prevent reoccurrence.