Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0721039	03/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center Of Frederick Llc,The	1475 Taney Avenue, Frederick, MD	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the chemistry proficiency testing (PT) attestation worksheets and interview with the laboratory supervisor (LS), the laboratory failed to ensure that all the testing personnel (TP) who tested bilirubin samples performed PT. Findings: 1. The laboratory currently has fifteen TP listed on the "Laboratory Personnel Report" (CMS-209) who perform bilirubin testing. 2. A review of chemistry PT attestation worksheets from the third event in 2023 though the first event in 2025 showed that PT was performed by three of the fifteen TP in five events reviewed. 3. During the survey on 03/12/2025 at 11:30 AM, the LS confirmed that PT samples were not tested each year by all the staff who perform bilirubin testing to ensure accurate and reliable patient test results.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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.

	This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory supervisor (LS), the laboratory failed to ensure that the attestation worksheets were signed and retained according to the instructions PT provider instructions for all disciplines performed in the laboratory. Findings: 1. The chemistry PT records from the third event in 2023 through the third event in 2024 were reviewed. 2. The PT attestation worksheets showed that the name of the "analyzer" /testing person (TP) had not been entered onto the PT database. The printed forms did not list the "analyzer" along with the signature of the TP and the date each test was performed. The name of the laboratory director (LD) was typed onto the form, but the signature and date of the LD was not present showing that the forms had been reviewed prior to submission. 3. During the survey on 03/12/2025 at 11:30 AM, the LS confirmed that the PT attestation worksheets failed to have the signature and date of each TP and the LD attesting that the samples were tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.