

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0886119	(X3) Date Survey Completed 12/11/2024
Name of Provider or Supplier Pediatric Center, The	Street Address, City, State 556 Central Ave, New Providence, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Testing Personnel 1 (TP1) as listed on the CMS 209 form, the laboratory director (LD) failed to sign attestation statements for Hematology Proficiency Testing (PT) events provided by American Proficiency Institute (API) from 1/1/23 to 12/11/24. The finding includes: 1. Review of PT records revealed the LD did not sign the attestation statements for all three Hematology PT events in 2023 and the 2nd event of 2024. 2. TP1 confirmed on 12/11/24 at 11:35 am the LD did not sign the attestation statements for the above mentioned PT events.</p>