

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0934515	(X3) Date Survey Completed 10/25/2018
Name of Provider or Supplier Pediatric Center Inc, The	Street Address, City, State 927 Se 1st St, Belle Glade, 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
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 record review and interview with laboratory personnel, the laboratory did not have signed attestations for all of the proficiency testing performed for the past two years. Findings include: Review of proficiency testing records for the past two years on 10/25/18 revealed that some of the attestations were not signed, and some of the attestations were signed incorrectly. 1. For the second testing event of 2018, the attestation did not have the director's signature. 2. For the first, second, and third testing event of 2017, the testing person signed the attestation as testing person and director. During an interview with testing person A. at 10:00 a.m., she said that signing as the director was a mistake and that the director signed electronically when he entered proficiency testing results, but we could not locate the signed attestation for the second event of 2018.</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory failed to get a score of 80% on all analytes in all testing events for the past two years.

Findings include: Proficiency testing record review for the past two years on 10/26/18 revealed that the laboratory failed received the following unsatisfactory scores. 1. For the second testing event of 2016, the laboratory received 40% for red blood cell count. 2. For the third testing event of 2017, the laboratory received 60% for white blood cell count and 67% for white blood cell differential. During an interview with the office manager at 10:15 a.m. on 10/25/18, she confirmed that they had had some unsatisfactory scores in the past.