

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2054110	(X3) Date Survey Completed 10/25/2018
Name of Provider or Supplier Pediatric Center Inc, The	Street Address, City, State 10075 Jog Rd Ste 308, Boynton 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
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 retain all proficiency testing records. Findings include: Review of proficiency testing records for the past two years on 10/25/18 revealed that there were records missing and signatures missing from records. 1. For the first testing event of 2018, there was no raw data from the cell counter and no data entry form. 2. For the second testing event of 2017, the director had signed the attestation, but the testing person had not. There was no performance evaluation form. 3. For the first testing event of 2017, there was no performance evaluation form. 4. For the third testing event of 2016, the attestation was signed by the director, but not the testing person. 5. For the second testing event of 2016, there was no performance evaluation form. During an interview with testing person A at 12:30 p.m. on 10/25/18, she acknowledged that there were forms missing.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory did not have documentation of calibration of the cell counter every six months as specified in their procedure manual. Findings include: The surveyor reviewed the procedure manual and the calibration records for the past two years on 10/25/18. The procedure for calibration indicated that the cell counter should be calibrated every 6 months. Review of calibration records and interview with testing person A at 12:40 p. m. on 10/25/18 revealed the only documented calibrations from 2016 to the present were 6/20/16, 2/16/17, 3/21/18, and 10/10/18.