

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2054110	(X3) Date Survey Completed 02/02/2023
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
D0000	An announced recertification survey was conducted on 2/2/23 at The Pediatric Center Inc, a clinical laboratory in Boynton Beach, Florida. The Pediatric Center Inc is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
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 staff interview, the laboratory failed to retain the Cell-Dyn Emerald instrument reports for their proficiency testing results for 2 of 3 events in 2022 and failed to retain attestation forms for 2 of 3 events in 2021 and 3 of 3 events in 2022. Findings include: 1. A record review of the American Proficiency Institute (API) proficiency test (PT) events for 2021 and 2022 showed that no records from the instrument (Cell-Dyn Emerald) used to perform the Complete Blood Count (CBC) were kept for the 2nd and 3rd testing events of 2022. 2. A record review of the API PT events showed no signed attestation forms were kept for the 1st and 2nd testing event of 2021 and the 1st, 2nd, and 3rd testing event of 2022. An interview with the Office Manager on 2/2/23 at 3:30 p.m. confirmed that the records from the</p>

	<p>instrument were missing and the attestation forms were not signed by the Laboratory Director or designee.</p>
<p>D2128</p>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document remedial action for unsatisfactory proficiency testing results for the 3rd American Proficiency Institute (API) Hematology testing event of 2021. Findings included: Review of the API proficiency test (PT) results for the 3rd testing event in 2021 showed that the lab had unsatisfactory scores on the following three Hematology analytes and there was no documentation of remedial action: 60% Red Cell Count (RBC) 60% Hematocrit (HCT) 60% Hemoglobin (HGB) During an interview on 2/2/23 at 3:30 p.m., the Office Manager confirmed that there was no documentation of remedial action for the three unsatisfactory scores.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure weekly maintenance was performed on the Cell Dyn Emerald analyzer for 2 of 2 years reviewed (2021 and 2022). The findings include: The Cell Dyn Emerald Instructions for Use booklet states, "Bleach Cleaning the system with a bleach solution is performed weekly and as needed if instrument use conditions cause frequent rejection of measured or quality control material out of range issues". The laboratory was unable to show documented weekly maintenance of the instrument. The interview with the Office Manager on 2/2/23 at 3:30 p.m. confirmed weekly maintenance was not documented.</p>
<p>D5437</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <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)</p>

(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 calibrate the Celldyn Emerald cell counter every six months per their procedure manual for two of two years reviewed. (2021-2022) The findings include: Review of the procedure manual on 2/2/23 showed that the laboratory's procedure was to calibrate the cell counter every six months. The calibration records show the cell counter was calibrated on 9/23/20, 6/4/21 (3 months late), 2/14/22 (2 months late), and 11/30/22 (3 months late). During an interview with the Office Manager on 2/2/23 at 3:30 p.m., it was confirmed that the machine had not been calibrated every 6 months.