

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2054110	(X3) Date Survey Completed 09/23/2020
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 9/23/20 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. The following is a description of the noncompliance.
D5437	<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) (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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not calibrate the cell counter every six months per their procedure manual. The findings included: Review of the procedure manual and calibration records on 9/23/20 revealed that the laboratory's procedure was to calibrate the cell counter every six months, but prior to the calibration performed on 9/23/20, the last calibration was performed on 8/6/2019. During an interview with testing person A at 11:30 a.m., on 9/23/20, she confirmed that the machine had not been calibrated since that 8/6/2019.</p>