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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0934515 | (X3) Date Survey Completed 09/23/2020 |
| 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 |
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| D0000 | An announced recertification survey was conducted on 9/23/20 at The Pediatric Center Inc, a clinical laboratory in Belle Glade, 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 9/16/20 revealed that the laboratory's procedure was to calibrate the cell counter every six months, but prior to the calibration performed on 9/16/20, the last calibration was performed on 10/1/2019. During an interview with testing person A at 9:25 a.m., on 9/23/20, she confirmed that the machine had not been calibrated since 10/1/2019.</p> |