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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0111054 | (X3) Date Survey Completed 04/27/2021 |
| Name of Provider or Supplier Pediatric Professional Associates Pa | Street Address, City, State 330 Ratzer Rd, Suite D20, Wayne, NJ | |
| 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 |
|---------------------------|---|
| 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 surveyor review of Calibration records and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Horiba ABX Micros 60 from 6/5/2020 to 3/19/2021. The TP # 2 as listed on CMS form 209 confirmed on 4/27/2021 at 11:00 am that the Calibration was performed only once in 2020.</p> |