

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1041960	(X3) Date Survey Completed 11/14/2023
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 21097 Ne 27th Ct, Aventura, 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 CLIA recertification survey was conducted at Pediatric Associates - Aventura on 11/14/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review the laboratory failed to follow manufacturer's instructions for Urinalysis Quality Control (QC) for two months (May 2022 and December 2022) out of 22 months reviewed (January 2022 to October 2023). Findings included: 1-Review of the Clinitek Status + QC logs revealed no QC was performed on May 2022 and December 2022. 2- Review of the "LAB 132 Urinalysis-waived" policy and procedure revealed that "2 Levels of quality controls are ran on the Multistix 10 SC with every new bottle of strips opened, shipment or monthly." 3 - Based on interview on 11/14 /2023 at 1:15 PM the Regional Laboratory Supervisor revealed that Urinalysis QC must be run every 30 days.</p>
D5429	<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>

This STANDARD is not met as evidenced by:
Based on Records reviewed, the laboratory failed to document Complete Blood Count (CBC) monthly maintenance on 7 out of 12 (January through December) months for 2022 and 2 out of 10 (January through October) months for 2023. Findings included: 1- Record review revealed that the Quality Control log "QC Review & System Maintenance CBC -CDS / Medonic M-series" was required to document in the four areas for Print QC/Data Logs, Reagent Log, Clean, and Clot Prevention. It was not documented for the following areas during the months and years indicated below: - February 2022 monthly Reagent log was not documented. - March 2022 monthly Clean and Clot Prevention were not documented. - May 2022 and June 2022 monthly Print QC/Data Logs, Reagent Log, Clean, and Clot Prevention were not documented - August 2022 monthly Clean and Clot Prevention were not documented - November 2022 monthly Print QC/Data Logs, Reagent Log, Clean, and Clot Prevention were not documented - December 2022 monthly Clean and Clot Prevention were not documented - January 2023 and May 2023 monthly Print QC/Data Logs, Reagent Log, Clean, and Clot Prevention were not documented 2- Interview on 11/14/2023 at 3:00 PM the Regional Laboratory Supervisor confirmed that the documentation was missing for CBC monthly maintenance.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

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, the laboratory failed to perform calibrations at least every 6 months according to the laboratory policy and procedures for one (2022) out of two years reviewed (2022-2023). Findings included: 1- Record review revealed one calibration was performed on 2/25/2022 for Total Bilirubin (TBili). Record review revealed one calibration was performed on 6/13/2022 for Complete Blood Count (CBC) 2- Review of the policy "LAB 116 Calibration of Laboratory Instruments" effective date 1/8/2011 revealed that calibration procedures must be performed and documented at least every 6 months. 3- Interview on 11/14/2023 at 1: 15 PM the Regional Lab Supervisor confirmed there were no other calibrations performed in 2022 for TBili and CBC.