

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0282786	<b>(X3) Date Survey Completed</b>  09/19/2024
<b>Name of Provider or Supplier</b>  Aventura Pediatrics Llc	<b>Street Address, City, State</b>  20750 W Dixie Hwy, Aventura, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on September 19th, 2024. AVENTURA PEDIATRICS LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5429</b>	<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 laboratory failed to perform maintenance as specified by the manufacturer for 21 out of 22 months reviewed (from November of 2022 to August 2024) for the Hematology Analyzer. Findings included: 1-Review of the Beckman Coulter DxH500 maintenance records revealed that monthly bleaching was not performed monthly for November and December of 2022, January to September of 2023, November and December of 2023, and January to August of 2024. 2-Review of the CMS 209 form submitted by the laboratory revealed there are three testing personnel TP1, TP2 and TP3. 3-Review of the instrument manual PN C42118AA Table 12.1 Matrix of Frequency for Cleaning Procedures stated that the "frequency for Performing a Bleaching Cycle as Every 1,000 cycles or monthly, whichever comes first." 4-Interview on 9/19/2024 at 12:33 PM with TP1 admitted to not performing the bleaching procedure monthly as specified by the manufacturer.</p>