

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0282786	(X3) Date Survey Completed 09/06/2022
Name of Provider or Supplier Aventura Pediatrics Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted from 08/25/2022 to 09/06/2022 found the AVENTURA PEDIATRICS LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and interview, the Laboratory Director (LD) failed to document the review and evaluation of the proficiency testing (PT) results for four out of five events reviewed for the Hematology specialty and for three out of five events for the Bacteriology sub-specialty in 2021 and 2022. Findings include: Review of College of American Pathologists (CAP) PT records, for 2021 and 2022 revealed that the LD failed to signed and date the Evaluation form for the following events: Year 2021 -Hematology first, second and third events. -Bacteriology first, second and third events. Year 2022 -Hematology second event. During an interview on 08/26/2022 at 2: 30 PM, the LD confirmed that she failed to sign and date the review of the PT events of reference.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a record review and interview, the laboratory procedure manual was not updated with the new Complete Blood Cell Count (CBC) analyzer in use since 11/11/2021 and the laboratory director (LD) failed to review and sign the procedure manual at least since 11/11/2021. Findings include: -Review of the laboratory procedure manual revealed that failed to include the procedure for the new CBC Beckman Coulter DXH 500 analyzer in use since 11/11/2021 -Review of the laboratory's procedure manual revealed that the laboratory director failed to sign and date the procedure manual at least since 11/11/2021. During an interview on 08/25/2022 at 02:35 PM, the LD acknowledged that the procedure manual was not updated with the new CBC analyzer and that she failed to review, sign and date it at least since 11/11/2021.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation and staff interview, the laboratory failed to label complete blood cells controls currently in use with the new expiration date. Findings include: - During the laboratory tour on 08/26/2022 at 10:00 AM, the surveyor observed that the laboratory had in use Beckman Coulter Tri Level Controls with Lot # 372213911, 372213912 and 372213913. The controls in use failed to have the opening date and the new expiration date. -Review of Beckman Coulter insert revealed that opened controls are stable for 16 days. During an interview on 08/26/2022 at 10:35 AM, the Testing Personnel # A, confirmed that controls in use were not labelled as described above and she explained that she started using the current controls on 08/10/2022.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to document the Quality Assurance activity since August 2020. Findings include: Review of the Monthly Quality Assurance Checklist records revealed no documentation of the QA activity since August 2020. During an interview on 08/25/2022 at 02:30 PM, with the Laboratory Director (LD), she confirmed that the laboratory failed to document the QA activity since August 2020.