

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0282786	(X3) Date Survey Completed 08/31/2026
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 desk review survey of the laboratory's proficiency test results was performed on 08/31/2026 for Aventura Pediatrics LLC. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2016 493.803(a)(b)(c) Condition: Successful Participation D6000 493.1403 Condition: Moderate Complexity Laboratory Director
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to examine or test Proficiency Testing (PT) samples with the laboratory's regular patient workload by Testing Personnel (TP) that routinely perform the testing in the laboratory for five out of five events reviewed Hematology and Bacteriology. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 08/31/2026 revealed the laboratory had four TP listed (TP#1, TP#2, TP#3 and TP#4). 2-Review of the procedure manual, policy titled, "PROFICIENCY TESTING POLICY GEN-010" signed by the LD on 09/03/2024, revealed that section "B. The PT samples must be tested with the laboratory's regular patient workload by the personnel who routinely perform the testing, using the laboratory's routine methods." Also, in section H "All testing personnel will participate in the PT testing on a rotating basis." 3-Review of College of American Proficiency (CAP) PT records for Hematology and Bacteriology for the following events 2024 (3rd), 2025 (1st, 2nd and 3rd), and 2026 (1st) revealed that TP#1 signed all attestations for the events of reference. The laboratory failed to have documentation of PT participation for TP #2, TP#3 and TP#4. 4-During an interview on 08/31/2026 at 01:20 PM, the LD confirmed that for all PT events

	reviewed, TP#1 was the TP and the rest of TP did not have participation in PT in the period reviewed.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review, review of the laboratory's College of American Pathologists (CAP) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email communication with the CAP PT program, the laboratory failed to successfully participate in the Specialty of Hematology for the analyte of Hematocrit (HCT) non-waived for 2 out of 2 testing events in 2024 and 2025.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review, review of the laboratory's College of American Pathologists (CAP) PT records and the review of the Centers for Medicare & Medicaid Services (CMS) Casper reports 153 and 155, and email communication with the CAP PT program, the laboratory failed to successfully participate in the Specialty of Hematology for the analyte of Hematocrit (HCT) non-waived for 2 out of 2 testing events in 2024 and 2025. Findings included: 1. Review of the laboratory's CAP PT records review of the CMS CASPER 153 and 155 reports revealed the following scores: A. Event #3 2024 HCT non-waived - 60% B. Event #1 2025 HCT non-waived - 60%
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform Bacteriology throat culture quality controls (QC) weekly in three out of three months reviewed. Findings Included: 1-Review of the Policy "THROAT CULTURE CONTROL "signed by Laboratory Director (LD) on 09/3/2024 revealed that the laboratory will do weekly a culture with a positive patient and if no positive patient available, the laboratory will send out outside for culture. 2- Review of patient log for Throat Culture for the following three months (January 2025, December 2025 and July 2026), revealed the following: a) January 2025: the previous QC was done on 12/27/2024, the laboratory did positive control (failed to identify the patient used), the laboratory failed to do QC on 01/03/2025 and tested six patients, the next QC documented was in 01/04/2025, 01/10/2025, 01/14/2025, 01/20/2025, 01/24/2025 (failed to identify the patient used). b) December 2025: QC on 12/02/2025 (failed to identify the patient used), failed to do QC on 12/09/2025 tested six patients, QC on 12/10/2025, 12/16/2025, 12/20/2025, (failed to identify the patient used), failed to do QC on 12/27/2025 tested one patient. c) July 2026: the previous QC was on 06/25/2026 (failed to identify the patient used), the laboratory failed to do QC on 07/02/2026 (one patient tested), 07/03/2026 (two patients tested), 07/06/2026 (one patient tested), 07/09/2026 (one patient tested), 07/13/2026 (five patients tested), QC done on 07/14/2026 (failed to identify the patient used), the laboratory failed to do QC on 07/21/2026 (tested two patients), 07/23/2026 (tested three patients), the laboratory did QC on 07/27/2026 ((failed to identify the patient used). 3-During an interview on 08/31/2026 at 12:40 AM, Testing Personnel #1 confirmed that the laboratory did not run controls on the days listed above

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor Proficiency Testing (PT) desk review, a review of the Centers for Medicare & Medicaid Services (CMS) Casper 155 and 155, the laboratory's College of American Pathologists (CAP) PT records, email communication with the CAP PT program, the Laboratory Director failed to provide overall management to ensure the laboratory performed PT in such a manner as to achieve and maintain satisfactory performance with successful PT in the Specialty of Hematology (See D6016).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor Proficiency Testing (PT) desk review, a review of the CMS Casper 155 and 155, the laboratory's College of American Pathologists (CAP) PT records, email communication with the CAP PT program, the Laboratory Director failed to ensure the laboratory performed PT in such a manner as to achieve satisfactory performance in PT in the Specialty of Hematology in 2024 and 2025 (See D2130).
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that one (TP#4) of four (TP#1, TP#2, TP#3, TP#4) Testing Personnel (TP) met the educational requirements. (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that one (TP#4) of four (TP#1, TP#2, TP#3, TP#4) Testing Personnel (TP) met the educational requirements since 01/28/2025. Findings included: 1-Review of the form CMS-209 Laboratory Personnel Report, signed and dated by the Laboratory Director (LD) on 09/01/2026, revealed that there were four moderate complexity TP listed (TP#1-TP#2, TP#3 and TP#4). 2-Review of personnel records revealed that TP#4 had no records. 3-Review of Hematology QC log records for Beckman Coulter DXH-500 analyzer, revealed TP#4 initials since 01/28/2025. 4- Random review of patient instrument print

outs for the Complete Blood Count (CBC) DXH-500, revealed patient results with TP#4 initials from 03/17/2025 to 05/26/2026. 5- During an interview on 08/31/2026 at 01:35 PM the Laboratory Director, confirmed that the laboratory failed to have documentation to proof that the TP#4 met the educational requirement.