Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0282786	09/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aventura Pediatrics Llc	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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 review of CMS Form 209, CAP (College of American Pathologists) proficiency testing for two-year period (2016 to 2018), and interview with testing personnel, the laboratory failed to rotate proficiency testing events to include all testing personnel who perform patient testing, for 6 of 6 events reviewed for hematology and bacteriology. The findings include: On September 20, 2018 at 12: 30pm, surveyor reviewed CMS form 209 completed by laboratory that had three testing personnel(#1, #2,#3) on the form. CAP proficiency testing record review for six events (2016-3rd event, 2017-three events, 2018-1st and 2nd event) revealed that (a) Testing person #1 performed only hematology proficiency testing for all six-test events. (b) Testing person #2 performed only bacteriology proficiency testing for all six-test events. During an interview on September 20, 2018, at 2:30pm, the testing person#1 confirmed that the testing person #1 and #2 performed both hematology and bacteriology patient testing but testing person #1 performed only hematology proficiency testing for all six-test events and testing person #2 performed only bacteriology proficiency testing for all six-test events. Testing person #3 was a new hire.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with testing person, laboratory failed to establish and follow written policies and procedures to access testing personnel competency for the two year record review period (9/2016 - 9/20/2018). The findings include: Laboratory Procedures and policy records reviewed on 9/20/18 at 1:30pm for two-year review period (9/2016 - 9/20/2018) did not show established policy to access testing personnel competency. There were no other personnel policy records to include the protocol to access testing personnel competency. During an interview on September 20, 2018, at 2:30pm, the testing person confirmed that the laboratory did not have the written policies and procedures to access testing personnel competency.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and an interview with the testing person, the laboratory failed to monitor and record the daily room temperature and humidity from 9/2016 to 9/18/2018 (for two-year review period) for hematology specialty. The findings include: On 9/20/2018 at 1:30pm, surveyor did not see daily temperature and humidity check in instrument maintenance and temperature record logs. Beckman Coulter hematology analyzer manual had optimal temperature range as 20* -25*C. During a laboratory tour at 2:15 PM, surveyor did not observe temperature and humidity monitoring device. During an interview on September 20, 2018, at 2:30pm, testing person confirmed that the laboratory did not have the room temperature and humidity-monitoring device, and did not monitor the laboratory temperature and humidity as part of the environmental requirement for Beckman Coulter Hematology analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on observation, record review and interview with testing person, laboratory failed to have the manufacturer's instructions -operator's manual for the recommended maintenance and function checks, and maintenance for Quest Diagnostics Horizon Mini E centrifuge. The findings include: During a laboratory tour on 9/20/18 at 2:00

	pm, surveyor observed Quest Diagnostics Horizon Mini E centrifuge with no manufacturer's instructions or operator's manual for the recommended maintenance and function checks. Maintenance record review at 1:30 pm did not show records for centrifuge maintenance. During an interview on September 20, 2018, at 2:30pm, the testing person confirmed that the laboratory - did not have manufacturer's instructions or operator's manual for the recommended maintenance and function checks for Quest Diagnostics Horizon Mini E centrifuge. - did not do maintenance on Quest Diagnostics Horizon Mini E centrifuge and had no records.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on interview with testing person and lack of competency performance records, technical consultant failed to access moderate complexity testing personnel annual competency for the two year record review period (9/2016 - 9/20/18). The findings include: Laboratory records reviewed on 9/20/18 at 1:30pm for two-year review period (9/2016 - 9/20/2018) did not show written documentation of moderate complexity testing personnel annual performance evaluations for testing person #1, #2, or #3. During an interview on September 20, 2018, at 2:30pm, the testing person #1 confirmed that the technical consultant did not perform annual performance evaluation for #1 or #2 for the years 2016 to 2018 or before. Testing person #3 was a new hire less than six months, and so was not due yet for the semiannual or annual performance evaluation.