

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0282786	<b>(X3) Date Survey Completed</b>  08/31/2020
<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 conducted on 8-31-2020, found that Aventura Pediatrics LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited : D5200- General Laboratory Systems D6063- Laboratory Testing Personnel
<b>D2020</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to obtain a passing score of 80 percent for Bacteriology in the 2nd proficiency testing (PT) event for the College of American Pathologist (CAP) in 2019 . Findings Included: Review of CAP proficiency testing record revealed a score of 60 percent was received for the specialty of Bacteriology in the 2nd PT event of 2019. An interview on 8/31/2020 at 12:19 pm, with the laboratory director confirmed that the laboratory failed to receive a passing score of 80 percent for Bacteriology in the 2nd proficiency testing (PT) event in 2019 .</p>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p>

	<p>This CONDITION is not met as evidenced by:  Refer to D5209 :Based on record review and staff interview, the laboratory failed to follow their policy and failed to perform competency assessments for testing personnel (TP).</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b>  CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  This is a repeat deficiency from 10-19-2018. Based on record review and staff interview, the laboratory failed to follow their own policy and failed to perform competency assessments for testing personnel (TP). Annual competency assessment was not performed for 1 (TP#A) out of 2 TP in 2019 and 2020. Initial and 6-month competency assessments were not performed for 1 (TP#B) out of 2 TP in 2019. Finding Include: . Review of CMS -209 Laboratory Personnel Form confirmed staff #A and staff #B are TP. Review of Personnel Competency assessment record showed TP#A had no documentation of performed annual competency assessments for 2019 and 2020. T#B had no documentation of performed initial and 6-month competency assessments. An interview on 8/31/2020 at 12:19 pm, with the laboratory director confirmed that the annual, initial and 6-month competency assessments were not done for TP in 2019 and 2020.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b>  CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:  Refer to D6065 : laboratory failed to ensure 1 (TP#A) out of 2 testing personnel (TP) has documentation of a high school diploma</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b>  CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of</p>

Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(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 1 (TP#A) out of 2 testing personnel (TP) has documentation of a high school diploma . Findings Include: Review of CMS -209 Laboratory Personnel Form confirmed that staff #A is TP. Review of Employee Records revealed that TP#A had no documentation of a high school diploma . An interview on 8/31/2020 at 12:19 pm, with the laboratory director confirmed TP#A had no documentation of high school diploma .