

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0975927	<b>(X3) Date Survey Completed</b>  12/22/2020
<b>Name of Provider or Supplier</b>  Beachside Pediatrics Llc	<b>Street Address, City, State</b>  1145 Kane Concourse, Bal Harbour, 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 12/22/2020 found that the Beachside Pediatrics LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited: -D5400 -D6063
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with laboratory director (LD), the laboratory failed to follow manufacturer's instructions for monitor room temperature and humidity for 2 out of 2 years (2019-2020). See D5413</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by:  Based on observation and laboratory director (LD) interview, the laboratory failed to document room humidity and temperature requirement to ensure optimal operation for the Coulter Ac-T Diff 2 Analyzer for 2 out of 2 years reviewed (2019 and 2020). This is a repeated deficiency from the previous survey. The findings include: An observation of laboratory on 12/22/2020 at 10:00 am, indicated that no thermometer and hygrometer located by the analyzer. A review of Coulter AcT diff2 Hematology Analyzer manual revealed a requirement for optimal operation a range of room temperature of 16 to 35 C and Humidity between 20 to 85 %. A review of temperature logs for 2019 and 2020, revealed no documentation of room humidity and temperature. During an interview on 12/22/2020 at 10:00 am the LD confirmed that there was no documentation of the room temperature and humidity for the period of reference.</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:  Based on record review and laboratory director (LD) interview, the laboratory failed to verify the education of 1 out of 1 Testing Personnel. See D6065</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 Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by:  Based on record review and laboratory director (LD) interview, the laboratory failed to verify the education of 1 out of 1 testing personnel (TP). Findings include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 12/22/2020 listed 1 TP. -Review of employee files revealed that there was no diploma to document the High School minimum requirement for TP. During an interview on 12/22/2020 at 11:30 AM with LD, she confirmed that the laboratory failed to have documentation to proof that the TP fulfill the minimum education requirement.</p>