

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D0236407	<b>(X3) Date Survey Completed</b>  04/19/2021
<b>Name of Provider or Supplier</b>  Upc-Pediatrics Associates	<b>Street Address, City, State</b>  7 Chenoweth Drive Ste A, Bridgeport, WV	
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>	An announced, on site, recertification survey was conducted at UPC Pediatric Associates on April 19, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<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 a review of the daily environmental condition logs, the laboratory policies and procedures (P&amp;P), and an interview with the laboratory manager, the laboratory failed to monitor and document (3) humidity for the ACT Diff analyzer. Findings: 1. Review of 2020 and 2021 environmental condition logs identified no humidity level was recorded for 15 of 15 months reviewed. 2. Review of P&amp;P revealed a CLIA Compliance Manual that contained defined environmental criteria: "the ACT Diff series analyzer operates at ambient temperature of 16-35 degrees Celsius and 30-85% humidity without condensation." 3. During an interview with the laboratory manager, on 4/19/21 at approximately 11:45 AM, the laboratory manager stated that the humidity for the room where the ACT Diff analyzer was located was not being monitored or documented.</p>