

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0980560	<b>(X3) Date Survey Completed</b> 09/21/2021
<b>Name of Provider or Supplier</b> Acme Pediatric Provider, Pllc	<b>Street Address, City, State</b> 2318 E Harrison Ave, Harlingen, TX	
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>	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor revised expiration dates for the current open vials of Boule Con-Diff controls. The findings included: 1. Surveyor observation on September 21, 2021 at 11:15 hours found three vials of Boule Con-Diff controls for used for quality control testing for the Medonic M-series hematology analyzer. Level: Low Lot 22107-01 Manufacturer Expiration date (unopened): 11-23-2021 Level: Normal Lot 22107-02 Manufacturer Expiration date (unopened): 11-23-2021 Level: High Lot 22107-03 Manufacturer Expiration date (unopened): 11-23-2021 2. Review of the Boule Con-Diff manufacturer package insert (201043L R03.31.15) stated, "Open vial stability 14 days after opening when returned to refrigerator after each use." 3. Without documenting the revised expiration date, the laboratory does not have a mechanism in place to ensure controls are not used beyond the 14 day open manufacturer date. 4. An interview with Testing Personnel #1 (as listed on Form CMS-209) on September 21, 2021 at 11:15 hours in</p>

the laboratory confirmed the findings. When asked when the controls were opened, she stated, "September 15th," and when asked if it was documented anywhere, she stated, "No." CMS - Centers for Medicare and Medicaid