Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0980560	03/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Acme Pediatric Provider, Pllc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. 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 follow the manufacturer's instructions to ensure kit packing is not opened until ready to use. The findings were: 1. Surveyor observation at 13:40 hours in the laboratory revealed two (2) BD Veritor test cartridges opened and removed from their foil packaging and located on the counter. 2. Review of the manufacturer's instructions for the BD Veritor System (8087667(13)) under, "Prepare for Testing" it stated, "Remove one RV Reagent D tube /tip and one BD Veritor System Flu A + B device from its foil pouch immediately before testing." 3. At the time of the observation, there were no patients with pending tests to be performed. 4. Interview with testing person #1 (as listed on Form CMS 209) on March 5, 2019 at 13:48 hours in the laboratory confirmed the findings. Key: BD - Becton Dickinson CMS - Centers for Medicare and Medicaid Services
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of quality control records, and

	confirmed in interview of facility personnel, the laboratory's policy for "Quantitative Control Validations" failed to reflect the laboratory's current practice. The findings were: 1. Review of laboratory policy titled, "Quantitative Control Validations" approved by the laboratory director on November 26, 2018, stated, "Method: New controls shall be run at least once a day for 5 days along with current controls ..." 2. Review of quality control records revealed that the laboratory's practice was to perform a 3-event (all ran on the same day) verification of new lots of controls. 3. The laboratory's policy did not reflect its current practice. 4. According to the CMS-116, the laboratory performed 21,600 hematolgoy (CBCs) tests annually 4. The findings were confirmed in interview of the technical consultant on March 5, 2019 at 14:30 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure each reagent was labeled with identification of contents, lot numbers, and expiration dates. The findings were: 1. Surveyor observation made in the laboratory on March 5, 2019 at 14:15 hours found two Medline containers (Reference #RL16CN1) filled with clear liquid. The containers were not labeled with content identification, lot number, or expiration dates. 2. The findings were confirmed in interview with testing person #1 (as listed on Form CMS 209) on March 5, 2019 at 14:15 hours in the laboratory. She confirmed that one was bleach but was unsure of what the other container was. She stated that it might be, "Something one of the nurses left in the laboratory." Key: CMS - Centers for Medicare and Medicaid Services