Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1006441	11/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Acme Pediatric Providers, Pllc	500 North Sam Houston Blvd, Suite 2, San Benito, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Academy of Family Physicians proficiency testing records from 2022, and staff interview, it was revealed the laboratory failed to ensure 2 of 5 testing personnel participated in proficiency testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 5 testing testing personnel. 2. A review of the laboratory's American Academy of Family Physicians proficiency testing records from 2022 (events 1, 2, and 3) revealed the laboratory failed to have documentation of 3 of 5 testing personnel participating in proficiency testing. They were (as listed on Form CMS 209): Testing personnel number 2 Testing personnel number 3 Testing personnel number 4 3. The laboratory was asked to provide documentation of the identified personnel participating in proficiency testing. No documentation was provided. 4. An interview with the technical consultant on 11/30/2022 at 830 hours in the break room confirmed the findings.
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's room temperature records from June 2022 to October 2022, and staff interview, it was revealed the laboratory failed to have documentation of corrected actions when documented room temperatures were outside the laboratory's defined acceptability range. The findings include: 1. A review of the laboratory's Room Temperature/Humidity logs from June 2022 to October 2022 revealed the laboratory's established acceptable room temperature range was 64.4 - 77 degrees Fahrenheit. 2. Further review of the records revealed the following days when the documented temperature was outside the acceptable range, however the laboratory failed to have documentation of performing corrective actions: Date Temp 6/3 78 6/24 78 6/28 79 7/12 78 8/12 78 8/23 78 9/15 78 10/7 78 3. The laboratory was asked to provide documentation of corrective actions being performed. No documentation was provided. 4. An interview with the technical consultant on 11/30/2022 at 930 hours in the break room - after his review of the records- confirmed the findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from August 2022 to November 2022, and staff interview, it was revealed the laboratory failed to have documentation of the notification of 9 of 9 critical values. The finding include: 1. A review of the laboratory's policy titled "Critical Values" (approved by the laboratory director on 11/8/2018) revealed the laboratory had the following defined critical values: White Blood Cells under 2 or greater than 20.0 Hemoglobin under 7.5 or greater than 18 Hematocrit under 25 or greater than 55 Platelets under 50 or greater than 800 2. A review of the laboratory's policy titled "Reporting Critical Values" (approved by the laboratory director on 11/8/2028) revealed: "It is the policy of this laboratory to document the reporting of Critical Values. Document: - who was notified - when was the person notified - by who was the person notified." 3. A review of patient test records from August 2022 to November 2022 identified the following 9 results which met the laboratory's criteria as a critical result: Date Seq Value 08/08 6943 WBC: 21.0 09/29 7386 WBC: 23.8 10/03 7421 WBC: 20.6 10/05 7452 WBC: 20.5 11/07 7751 WBC: 20.5 11/09 7779 WBC: 20.1 11/11 7807 WBC: 20.8 11/21 7866 WBC: 25.1 11/22 7875 WBC: 26.8 4. The laboratory was asked to provide documentation of the notification of the critical values to the provider. No documentation was provided. 5. An interview with the technical consultant on 11/30 /2022 at 1000 hours in the break room - after his review of the records- confirmed the findings. Key Seq - Sequence WBC - white blood cell