Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1006441	10/08/2024
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
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 review of manufacturer's instructions for the Piccolo Comprehensive Metabolic Panel cassette, review of the laboratory's quality assurance reports from November 2023 and December 2023, review of patient test records from November 2023 to January 2024, and staff interview, the laboratory failed to following manufacturer's instructions by ensuring quality control testing was acceptable prior to testing patient samples on 3 of 4 test dates. The findings included: 1. The manufacturer's instructions for the Piccolo Comprehensive Metabolic Panel (March 2015 PN:400-7139-1 Rev. P) stated: "Do not report results if controls are outside the labeled limits." 2. A review of the laboratory's quality assurance report from November 2023 determined the laboratory identified quality control results for the analyte Total Bilirubin failed on 11/17/2023 and 12/01/2023. The quality assurance report stated: "Please consider reported patient tests to be invalid for procedures that had controls out of limits. And: a) Retrieve patient record and indicate that the test result was invalid. b) Make the correction, but don't white out or erase the previous result. You may make one line through it, but don't erase. c) Notify the requesting physician of the error and request permission to repeat the test. d) Keep a record in lab of what happened." 3. A review of the laboratory's quality assurance report from December 2023 determined the laboratory identified quality control results for the analyte Total Bilirubin failed on 12/08/2023. The quality assurance report stated: "Please invalidate patients performed 12/08 and 01/04/2024." 4. Quality control materials were with each new lot, shipment, or every 30 days on the Piccolo analyzer.

	5. A review of patient test records from November 17, 2023 to November 29, 2023 identified 64 patients were tested and reported after the quality control failure (see patient alias list 1). 6. A review of patient test records from December 8, 2023 to January 4, 2024 identified 80 patients were tested and reported after the quality control failure (see patient alias list 2). 7. The technical consultant confirmed the findings in an interview conducted on 10/08/2024 at 1140 hours in the break room.
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: NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/30/2022. Based on review of the laboratory's submitted CMS 209 Form, review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 and 2024, and staff interview, the laboratory failed to ensure 3 of 4 testing personnel participated in proficiency testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 5 testing testing personnel. Four of the five testing personnel were employed by the facility in 2023 and 2024 at the time proficiency testing was performed. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 (events 1, 2, and 3) and 2024 (events 1 and 2) revealed the laboratory failed to have documentation of 3 of 4 testing personnel participating in proficiency testing. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 2 Testing personnel number 5 3. The technical consultant confirmed the findings in an interview conducted on 10/08/2024 at 0920 hours in the break room.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing policy, review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 and 2024, and staff interview, the laboratory failed to ensure proficiency testing samples were tested the same number of times as patient samples for 1 of 5 events. The findings included: 1. A review of the laboratory's proficiency testing policy (approved 11/8/20218) stated: "PT specimens are to be treated the same as patient samples." Patient samples were routinely only tested once. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 (events 1, 2, and 3) and 2024 (events 1 and 2) revealed the laboratory tested proficiency testing samples multiple times on 1 of 5 events. The proficiency testing samples from 2024 Event 2 were tested twice. Sample: HSY-6 tested: 7/19/2024 10: 13 7/19/2024 10:23 Sample: HSY-7 tested: 7/19/2024 10:16 7/19/2024 10:25 Sample: HSY-8 tested: 7/19/2024 10:18 7/19/2024 10:26 Sample: HSY-9 tested: 7/19/2024 10: 20 7/19/2024 10:28 Sample: HSY-10 tested: 7/19/2024 10:21 7/19/2024 10:29 3. The

	technical consultant confirmed the findings in an interview conducted on 10/08/2024 at 0920 hours in the break room.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from September 2024, review of the laboratory's patient test records from September 2024, and staff interview, the laboratory failed to ensure quality control material was not expired prior to use on 1 of 23 test days. The findings included: 1. A review of the laboratory's quality control records from September 2024 determined the laboratory tested expired quality control material prior to testing patients on 1 of 23 days. On September 24, 2024 the following expired control material was tested: Low control: Lot 2240501 expiration date: 9/23/2024 Normal control: Lot 24440502 expiration date: 9/23/2024 2. A review of patient test records from September 24, 2024 determined the following patients were tested: Sequence: 3888 Sequence: 3889 Sequence: 3890 Sequence: 3891 After the patients were tested, the laboratory calibrated the instrument and tested new lots of control material. The patient samples were not retested after the acceptable controls. 3. The technical consultant confirmed the findings in an interview conducted on 10/08/2024 at 0950 hours in the conference room.
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: NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/30/2022. Based on review of the laboratory's policies, review of patient test records from September 2024, review of the laboratory's critical value log from May 2024 to October 7, 2024, and staff interview, the laboratory failed to have documentation of the notification of 4 of 5 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 September 2024 identified the following 5 results which met the laboratory's criteria as a critical result: Date Seq Value 09/03 3722 WBC: 20.4 09/03 3726 WBC: 44.4 09/23 3879 HBG: 18.8 09/24 3915 HCT: 567 09/24 3921 PLT: 19 4. A review of the laboratory's critical value log from September 2024

	determined the following 4 critical values were not documented: Date Seq Value 09 /03 3722 WBC: 20.4 09/23 3879 HBG: 18.8 09/24 3915 HCT: 567 09/24 3921 PLT: 19 5. An interview with the technical consultant on 10/08/2024 at 1100 hours in the break room - after his review of the records- confirmed the findings. Key Seq - Sequence WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet