

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1006441	<b>(X3) Date Survey Completed</b>  10/17/2018
<b>Name of Provider or Supplier</b>  Acme Pediatric Providers, Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>The laboratory was surveyed on October 17, 2018. The facility was not in compliance with the following CLIA Conditions at 42 CFR part 493: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6056 - 42 C.F.R. 493.1415 Condition: Laboratories performing moderate complexity testing - Clinical Consultant Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any changes in- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). Review of the "Stock Purchase Agreement" revealed the agreement was "Signed December 6, 2016, but is effective as of October 17, 2016 (the "Effective Date"). The laboratory did not notify CLIA of a change in ownership within 30 days of its changes. The laboratory did not notify CLIA of a laboratory director change within 30 days of its changes.</p>
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to monitor revised expiration dates on i-STAT Chemistry 8 test cartridges. The findings were: 1. Direct observation made in the laboratory on October 17, 2018 at 09:20 hours revealed 3 Abbott i-STAT Chemistry 8 test cartridges on the laboratory counter. The cartridges did not have a revised expiration date on them. According to testing personnel two (as listed on Form CMS 209), the cartridges had been at room temperature for, "About three days." 2. Review of the manufacturer's</p>

instructions on the package labeling for the Abbott i-STAT Chemistry 8 test cartridges revealed room temperature storage is 14 days. 3. An interview with testing person 2 (as listed on Form CMS 209) on October 17, 2018 at 09:05 hours in the laboratory confirmed the findings. When asked if the laboratory documents the date the cartridges are put at room temperature, she stated, "No." Key: CMS - Centers for Medicare and Medicaid Services

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of manufacturer's instructions, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to monitor overall quality of its analytic systems as evidenced by: 1. The laboratory failed to resolve flags on CBCs prior to their release to the healthcare provider. (refer to D5403). This is a repeat deficiency. 2. The laboratory failed to follow the manufacturer's instructions to re-analyze samples with system messages prior to their release to the healthcare provider. (refer to D5411)

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the operator's manual, the laboratory's procedure manual, and staff interview it was revealed that the laboratory's policy for CBCs with flags failed to resolve flags on the Medonic M-series hematology analyzer prior to their release to

the healthcare provider. The findings were: 1. This is a repeat deficiency from the survey dated October 27, 2016. 2. A review of the Medonic M-series Operator's guide section 9.2 titled "System Information and Messages" pages 70 -73 revealed the following 27 flags: AF, DE, FD, HF, HH, HL, HN, HO, HS, OR, SE, TE, EC, ER, NR, DF, DP, LF, LP, ST, TB, TL, TU, BD, NM, OM and TM. The Operator's guide states, that for flags BD, NM, OM and TM, the required action is: "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results". 3. A review of the laboratory's procedure manual revealed the laboratory's policy titled, "Actions Protocol for WBC Differential Flags" signed by the laboratory director (no approval date) stated, " ...If the flags persist, then send an EDTA Tube that may be transported for testing at a reference laboratory." And; "Alternate Action: The Auto Diff section exhibiting the flags may be blocked off and not reported. The provider will make assessment of the patient without that portion of the report and only using th hemogram parameters." 4. Random review of patient results from August, September, and October 2018 revealed the following patient results retrieved from the laboratory's EMR (Electronic Medical Record) that revealed flags were not resolved prior to their release to the healthcare provider. Sequence Number: 9375 Date: August 7, 2018 Flag: BD Sequence Number: 9419 Date: August 14, 2018 Flag: BD Sequence Number: 9451 Date: August 20, 2018 Flag: BD Sequence Number: 9500 Date: August 27, 2018 Flag: OM Sequence Number: 9731 & 9732 (1st and 2nd run) Date: October 1, 2018 Flag: OM 5. An interview with testing personnel two (as listed on Form CMS-209) on October 17, 2018 at 10:30 hours in the office confirmed the findings. After her review of the records, she agreed that the flags had not been resolved. Key: CMS - Centers for Medicare and Medicaid Services

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
Based on review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to re-analyzer samples with information messages prior to their release to the healthcare provider. The findings were: 1. Review of the manufacturer's instructions for the Medonic M Series hematology analyzer under, "System Information Messages" listed the following system messages and the corresponding corrective action:" Flag: FD Message: RBC/PLT - Irregular Distribution Action: Re-analyze sample Flag: BL Message: Result is below linearity Action: Re-analyze sample Flag: SE Message: Measurement Statistics Warning: re-analyze Action: Re-analyze sample 2. Random review of patient results from August, September and October 2018 revealed the following patient results were resulted and released to the healthcare provider when the flags had not been reanalyzed as required by the manufacturer: Sequence Number: 9609 Date: September 13, 2018 Flag: SE Sequence Number: 9635 Date: September 18, 2018 Flag: BL Sequence Number: 9706 Date: September 27, 2018 Flag: FD 3. An interview with testing personnel two (as listed on Form CMS-209) on October 17, 2018 at 10:30 hours in the office confirmed the findings. After her review of the records, she agreed that the flags had not been resolved Key: Centers for Medicare and Medicaid Services

**D6056**

**CLINICAL CONSULTANT**

CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:

Based on a review of the CMS laboratory Personnel Report, CMS-116, laboratory records and confirmed in interview the facility the laboratory failed to employ personnel to provide clinical consultation. (refer to D6057) Key: CMS- Centers for Medicare & Medicaid Services

**D6057**

**CLINICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on review of the Form CMS 209, review of laboratory job descriptions, and staff interview, it was revealed the laboratory failed to have a person designated as the clinical consultant. The findings were: 1. A review of Form CMS 209 signed by the laboratory director on 10/10/2018 revealed the laboratory did not have a person listed on the form designated as the clinical consultant. 2. Review of the laboratory's job description for "Role of Clinical Consultant" stated, "Qualifications: -Qualified as a Laboratory Director under CLIA or -M.D., D.O. with current medical license in state of laboratory's location or -The Medical Director or Owner (Licensed physician) may function as Clinical Consultant of the Laboratory and is available to consult with and to provide opinions to the Physician Assistants employed and to Laboratory clients concerning diagnosis, treatment and management of patient care." 3. The above findings were confirmed in interview with testing person two (as listed on Form CMS 209) at 09:00 hours. After her review of the Form CMS 209 and asked if the laboratory has a clinical consultant, she stated, "As far as I know we just have a technical consultant." Key: M.D. - medical doctor D.O. - doctory of osteopathy CMS - Centers for Medicare and Medicaid Services