

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0982892	<b>(X3) Date Survey Completed</b>  03/07/2019
<b>Name of Provider or Supplier</b>  Prattville Pediatric Assoc	<b>Street Address, City, State</b>  645 Mcqueen Smith Rd, Prattville, AL	
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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter AcT diff 2 Operator's Manual, calibration and quality control records, and an interview with the Laboratory Manager, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC), for three out of four calibrations of the Hematology analyzer performed in 2017 - 2018. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff 2 revealed the instrument was calibrated on the following dates: A.) 6/09/2017 at 12:13 PM B.) 12/27/2017 at 9:51 AM, and C.) 12/12/2018 at 2:21 PM However, there was no documentation QC was run after these calibrations. 2. A review of the Coulter AcT diff Operator's Guide, under the CALIBRATION section on page 5-18 revealed, "... 17. Verify calibration by running 4C PLUS Cell Control. ..." 3. During an interview on 3/7/2019 at 2:35 PM, the surveyor reviewed with the Laboratory Manager, Coulter's directions to perform QC after calibration of the Hematology analyzer. The Manager then checked with Testing Personnel #1 who stated she did perform QC after calibrations. However the laboratory only provided QC performed in the early</p>

morning (before the calibrations) for the above dates, thus the above noted findings were confirmed. .

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a lack of training documentation in the personnel files for Testing Personnel (TP) #4, #5, and #6, and an interview with the Laboratory Manager, the Laboratory Director failed to ensure training for three of three new testing personnel was documented before patient testing began. The Director further failed to ensure TP #1 was trained to perform calibrations of the Beckman Coulter AcT diff 2 Hematology analyzer as per manufacturer's instructions. [Refer to D5437 for further details.] The finding include: 1. A review of the employee records provided for TP #4 (hired December 2017), #5 (hired November 2017), and #6 (hired May 2018) revealed no documentation of training. A generic "Laboratory Personnel Evaluation" was completed, however the facility did not specify the tests for which the personnel were trained, or the details and extent of the training. The surveyor further noted these testing personnel had not participated in the proficiency testing in 2017-2018. [The laboratory failed to provide evidence the sixth standard on the Personnel Evaluation form, "Accuracy in test performance...with PT or blind samples" had been assessed to ensure their training had been sufficient.] 2. A further review of the personnel records revealed the a letter for each of the above testing personnel. The following letter was signed by the Laboratory Director, "Effective [ Date ] [ Name of Employee ] has been adequately trained to perform laboratory procedures at Prattville Pediatric Associates.". 3. The surveyor further noted the Laboratory Director had failed to ensure TP #1 was correctly trained to follow the manufacturer's instructions when performing three out of four calibrations on the Beckman Coulter AcT diff 2 Hematology analyzer in 2017-2018. [Refer to D5437 for additional details..] 4. During an interview on 3/7/2019 at 11:30 AM, the surveyor asked the Laboratory Manager about the scope of responsibilities for TP #4, #5, and #6. The Manager stated the testing personnel performed patient CBC (Complete Blood Count) testing on the Beckman Coulter AcT diff 2 automated Hematology analyzer, and waived testing. The surveyor then asked how the training was documented; the Manager stated the laboratory considered the letter signed by the Laboratory Director (see #2 above) as documentation of the training. The Manager confirmed the laboratory did not use a manufacturer's training checklist or a lab-developed training list that detailed the employee's training and responsibilities. SURVEYOR ID#32558 Licensure and Certification Surveyor