

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2126498	<b>(X3) Date Survey Completed</b>  08/07/2019
<b>Name of Provider or Supplier</b>  Medcenter Primary Care Pc	<b>Street Address, City, State</b>  4960 Rice Mine Road Ne Suite 10, Tuscaloosa, 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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter AcT diff 2 Hematology analyzer Operator's Manual and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director signed, dated and approved the manual for use by the testing personnel. The findings include: 1. A review of the Beckman Coulter AcT diff 2 Operator's Manual revealed no signature and date of the Laboratory Director to indicate review and approval of the manual for use by the testing personnel. 2. During an interview and review of the manual on 8/7/2019 at approximately 10:45 AM, the surveyor asked about the Laboratory Director's review of the Hematology procedures in use. Testing Personnel #1 stated she had forgotten to give the Operator's Manual to the Director for his signature (to indicate his approval). .</p>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on a review of installation and validation documentation for the Beckman Coulter AcT diff 2 Hematology analyzer, and interviews with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the initial installation and verification procedures included documentation of review by the Laboratory Director and Technical Consultant (as indicated by signatures and dates of reviews) before patient testing began on 3/25/2019. The findings include: 1. During the initial tour of the facility on 8/7/2019 from 8:45 to 9:00 AM, TP #1 included CBCs (Complete Blood Counts) on the moderate-complexity test menu for the laboratory. TP #1 stated the laboratory began performing CBCs for patients on 3/25/2019. 2. A review of the personnel records revealed the Laboratory Director had signed a letter designating the duties of the Technical Consultant (TC) to an outside qualified professional TC, who was listed on the Form CMS-209 (Laboratory Personnel Report). 3. A review of the records for the Beckman Coulter AcT diff 2 Hematology analyzer revealed the Coulter technical representative installed the instrument on 3/21/2019. 4. A further review of the installation records revealed Coulter LIN-C Linearity controls (a five level kit) were used to establish accuracy and reportable range on 3/21/2019. Values for each of the five parameters were hand-written on a "Coulter LIN-C Worksheet" by the Coulter technical representative; the instrument printouts of the raw data were retained in the binder. The Laboratory Director had signed on multiple pages, however there was no indication of when his review occurred (no date) to document the data was reviewed/approved before patient testing began. The surveyor further noted there was no signature or date documenting the Technical Consultant's review. 5. In an interview on 8/7/2019 from 10:40 AM, the surveyor asked if the Technical Consultant had reviewed the validation records for the Beckman Coulter AcT diff 2 analyzer. TP #1 stated she previously had a scheduled meeting while the TC was at another facility, however TP#1 had forgotten to include the validation records in the documentation for the TC's review. TP #1 stated the TC had not had a chance to review and approve the verification procedures. The surveyor explained the laboratory also needed the TC's review and approval since the Laboratory Director had delegated this responsibility. 6. As the interviewed continued on 8/7/2019 from 10:45 AM, the surveyor asked when the Laboratory Director had reviewed the Hematology analyzer validation. TP #1 stated "he signed everything on 3/25/2019". The surveyor then asked if the Director had dated his reviews to document the data was reviewed and approved before patient testing began; TP #1 was unable to find any record of the Director signature with a date of approval. Thus, the above noted findings were confirmed. SURVEYOR ID# 32558 Licensure and Certification Surveyor