

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2025667	<b>(X3) Date Survey Completed</b> 03/03/2022
<b>Name of Provider or Supplier</b> Mission Family Practice	<b>Street Address, City, State</b> 2630 E Citizens Drive, Fayetteville, AR	
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: Through a review of the manufacturer's requirements, documentation of calibrations, and interviews with laboratory staff, it was determined the laboratory failed to perform calibration with at least the frequency recommended by the manufacturer. Survey findings follow: A. A review of the operators' manual for the Coulter AcT Diff revealed the manufacturer of the requires calibration at least every six months. B. Through a review of calibration documentation it was determined the calibration of the AcT Diff was documented on January 2020, August 2020, and January 2021. There was no other documentation of the Coulter AcT Diff through the date that it was taken out of service in December 2021. C. In an interview at 11:02 on 3/3/2022, laboratory employee #3 (as listed on the form CMS-209) confirmed the calibration was not performed on time.</p>
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</p>

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Through a review of Personnel Records for eight of eight personnel listed on the form CMS-209, through a review of proficiency test documentation, and through interviews with laboratory staff, it was determined the laboratory director failed to give written authorization to one of six testing personnel who perform complete blood counts. Survey findings include: A. The surveyor reviewed Staff Laboratory Competency Checklists for six testing personnel (listed as #1 through #6 on the form CMS-209) who perform moderate complexity complete blood counts. The Staff Laboratory Competency Checklists included the statement, "The above employee has been authorized by Dr. Bonner to perform above tests." This form is the only form in the Personnel Records that includes an authorization to perform testing. The Laboratory Competency Checklist for laboratory employee #3 (as listed on the form CMS-209) did not include authorization to perform the CBC (complete blood count). Tests approved for employee #3 were Dipstick Urine, Influenza A & B, Rapid Strep, and Urine Pregnancy which are waived tests. The authorization had not been signed by the laboratory director. B. A review of proficiency test attestation sheets for the Second and Third Hematology Proficiency Test Events in 2021 revealed that laboratory employee #3 signed the attestation sheets as the testing personnel performing the complete blood counts on both events. Proficiency testing is to be performed by the laboratory personnel who routinely perform patient testing. C. In an interview, at 9:39 on 3/3/2022, laboratory employee #3 confirmed that she performs patient complete blood counts and that the authorization to test does not include authorization to perform them.