

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1013769	(X3) Date Survey Completed 11/01/2023
Name of Provider or Supplier Monfee Medical Clinic	Street Address, City, State 3812 West Main, Russellville, AR	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency test documentation for 2022 and 2023, the surveyor determined the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples. Survey findings include: A. The Surveyor reviewed the Proficiency Test documentation for the Second and Third Hematology Events of 2022 and the First and Second Hematology Events of 2023. Twenty of twenty proficiency test samples were tested in duplicate. Results for eight of the twenty samples repeated, were results that would be found in normal patients. B. Through a review of ten patient reports the surveyor determined patients were only repeated when results were abnormal or when flags were present on the initial report. C. In an interview, at 11:45 on 11/1/2023, laboratory employee #1 confirmed all proficiency samples were run in duplicate, including those whose results are within normal patient limits.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
A review of hematology quality control documentation for March, May, and October of 2023 revealed, on one of twenty-six days of testing in May 2023, the laboratory documented running only one level of hematology control. Survey findings follow: A. The surveyor reviewed quality control for March, May, and October 2023. On 5/23 /2023 the laboratory documented quality control results for the Low Hematology Control (lot #372314711) but did not document results for the Normal (lot # 372314712) and High (lot # 372314713) Hematology Controls. B. A review of patient hematology test results for 5/23/2023 revealed nine patients tested on the day that only one control was documented. C. During the interview at 11:45 on 11/1/2023, laboratory employee #1 confirmed that nine patients were tested on 5/23/2023 when only one control was documented for hematology.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Through a review of personnel records for the five testing personnel listed on the form CMS-209 and through interviews with laboratory staff, it was revealed the technical consultant failed to perform competency assessments using the six required methods for five of five testing personnel. Survey findings include: A. The surveyor reviewed competency assessments for the five testing personnel listed on the form CMS-209 as personnel #1 through #5. Competency assessments performed in 2022 and 2023 for five of five employees only had documentation of evaluation by direct observation of test performance. Competency assessments performed in 2022 and 2023 failed to have documentation of observation of maintenance, function checks, and calibration, assessment of problem solving, review of quality control, maintenance, and other records, review of proficiency test documentation, or monitoring recording/ reporting of test results. B. During an interview, at 11:45 on 11/1/2023, laboratory employee #1 (as listed on the form CMS-209) confirmed the competency assessments of the five testing personnel only had documentation of one method of assessment.