

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1045512	(X3) Date Survey Completed 06/15/2022
Name of Provider or Supplier Doctors Med Care Of Jacksonville Pc	Street Address, City, State 1505 Pelham Road S Suite 2, Jacksonville, AL	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION 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 a review of the Medonic M Series Hematology analyzer calibration records and an interview with the Technical Consultant, the laboratory failed to retain documentation for four out of four 2020 and 2021 calibration procedures. The findings include: 1. A review of the Medonic M Series Hematology analyzer records revealed the most current 2022 calibration performed on 5/9/2022. There were no records for the semi-annual calibrations performed in 2020 and 2021. 2. During an interview at 11:00 AM on 6/15/2022, the Technical Consultant stated the laboratory had performed the calibrations, and he had reviewed the documents, however the testing personnel were unable to locate 2020-2021 Hematology calibration binder. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records, a review of the policy and procedures, and an interview with the Technical Consultant (TC), the TC failed to evaluate the competency of moderate complexity testing personnel semiannually during the first year of patient testing. This was noted for one of two new testing personnel (TP) listed on the CMS Form 209 Laboratory Personnel Report. The findings include: 1. A review of the CMS Form 209 Laboratory Personnel Report revealed two testing personnel (TP #7 and #8) were hired since the previous survey. 2. A review of personnel records revealed TP #8 was recently hired in 2022. The files for TP #7 revealed she was hired and trained in November 2020. The records documented the semiannual competency was performed in May 2021, and signed by TP #1. There was no documentation of the Technical Consultant's semi-annual assessment of competency for TP #7. 3. A review of the policy and procedures manual revealed the Technical Consultant/Supervisor Responsibilities/Job Description which stated, "Evaluates and documents performance of individuals responsible for testing [at] six months... in the first year of employment". 4. During an interview at 12:38 PM on 6/15/2022, the TC confirmed the above noted findings, stating TP #1 performed the competencies because she was the "Supervisor" of the laboratory. The surveyor then confirmed TP #1 had a high school diploma, and then explained competency assessments in a moderate-complexity laboratory could only be delegated to an individual with the required educational credentials to perform the responsibilities of a Technical Consultant. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records, a review of the policy and procedures, and an interview with the Technical Consultant (TC), the TC failed to evaluate the annual performance of individuals performing moderate complexity-testing patient testing. This was noted for six out of eight testing personnel listed on the CMS Form 209 Laboratory Personnel Report. The findings include: 1. A review of the personnel records revealed Testing Personnel #1 performed and signed the annual competency assessments for Testing Personnel #2 through Testing Personnel #7. 2. A review of the policy and procedures manual reveals Technical Consultant/Supervisor Responsibilities/Job Description which states, "Evaluates and documents performance of individuals responsible for testing...[at] 12 months in the first year of employment and yearly thereafter". 3. During an interview at 12:38 PM on 6/15/2022, the TC confirmed the above noted findings, stating Testing Personnel #1 performed the competencies because she was the "Supervisor" of the laboratory. The surveyor then confirmed Testing Personnel #1 had a high school diploma, and then explained competency assessments in a moderate-complexity laboratory could only be delegated to an individual with the required educational credentials to perform the responsibilities of a Technical Consultant SURVEYOR ID#32558 Licensure and Certification Surveyor