

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 25D2146626	<b>(X3) Date Survey Completed</b> 06/27/2024
<b>Name of Provider or Supplier</b> Merit Health Internal Medicine Canton	<b>Street Address, City, State</b> 163 River Oaks Dr Ste 201, Canton, MS	
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 review of the CDS Medonic M-Series hematology analyzer procedure manual and calibration records, and interview with the office manager, the laboratory failed to perform calibration at a minimum of every six months, as recommended by the manufacturer, from 5-26-2022 until 6-27-2024 for three of four six-month periods. Findings include: 1. Review of the CDS Medonic M-Series hematology analyzer procedure manual revealed the calibration procedure states, "Calibration must be performed upon installation of the instrument and then at a minimum of every six months." 2. Review of calibration records for the CDS Medonic M-Series hematology analyzer from 5-26-2022 through 6-27-2024 revealed calibration was performed on 9-22-2022. No calibration was documented as performed for March 2023, September 2023 or March 2024. 3. The office manager confirmed in an interview on 6-27-2024 at 12:20 p.m. the calibration was not performed at a minimum of every six months as recommended by the manufacturer for three of four six-month periods reviewed.</p>
<b>D6029</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

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 review of laboratory testing personnel records, Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the office manager and testing personnel (TP) #3, the laboratory director failed to ensure one of three testing personnel listed on the CMS 209 personnel form had appropriate education and received the appropriate training for performing complete blood count (CBC) testing on the CDS Medonic M-Series hematology analyzer prior to testing patient specimens. Findings include: 1. Review of laboratory personnel records available the day of the survey revealed one of three TP had no documentation of education and initial training prior to performing patient testing. 2. The office manager confirmed in an interview on 6-27-2024 at 10:15 a.m. that TP #3 (date of hire 5/29/22) lacked documentation of education and initial training.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of laboratory quality control records for the CDS Medonic M-Series hematology analyzer and interview with the office manager, the technical consultant failed to document review of quality control records for 10 of 24 months to evaluate the competency of the staff. Findings include: 1. There was no review documented by the technical consultant for the CDS Medonic M-Series hematology analyzer quality control records from 8-1-2023 through 5-31-2024. 2. An interview with the office manager on 6-27-2024 at 11:30 a.m. confirmed there was no documented review of quality control records by the technical consultant for 10 of 24 months.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records, Centers for Medicare and Medicaid

Services (CMS) 209 personnel form, and interview with the office manager, the technical consultant failed to evaluate and document the performance for one of three testing personnel (TP) #3 responsible for moderate complexity testing at least semiannually during the first year this individual tested patient specimens. Findings include: 1. Review of laboratory personnel records since 5/26/2022 revealed no semiannual competency evaluation for the performance of the CDS Medonic M-Series complete blood count (CBC) testing by the technical consultant for one of three testing personnel. TP #3 was hired on 5-29-2022. 2. In an interview on 6-27-2024 at 10:30 a.m., the office manager confirmed no semiannual competency evaluation was performed on TP #3 by the 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 review of laboratory personnel records, Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the office manager, the technical consultant failed to evaluate and document the performance for one of three testing personnel (TP) #3 responsible for moderate complexity testing annually since this individual began testing patient specimens. Findings include: 1. Review of laboratory personnel records since 5-26-2022 revealed no documentation of annual competency evaluations for the performance of the CDS Medonic M-Series complete blood count (CBC) testing by the technical consultant for one of three testing personnel since date of hire on 5-29-2022. 2. In an interview on 6-27-2024 at 10:30 a. m., the office manager confirmed no annual competency evaluation was performed on TP #3 by the technical consultant.