

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1064250	(X3) Date Survey Completed 09/16/2025
Name of Provider or Supplier After Hours Clinic Sumiton	Street Address, City, State 292 Bryan Road, Sumiton, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour, a review of the Complete Blood Count (CBC) Quality Control (QC) package insert, and an interview with Testing Personnel 1 (TP1), the laboratory failed to write the new expiration dates on the QC vials after opening. The surveyor noted three of the three levels of QC currently in use had no open expiration dates recorded. The findings include: 1. During the laboratory tour on 09-16-2025 at approximately 9:18 AM the surveyor observed TP had not recorded the new expiration date on the CBC QC vials after opening. 2. A review of the Boule QC package insert revealed the manufacturer's open vial stability of 14 days. 3. During an interview on 09-16-2025 at 9:26 AM, TP1 stated TP utilized a new set of Hematology QC every 10-11 days, however they had failed to record the new open expiration date on the vials.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)</p>

(3)-- (a)(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 (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on reviews of the Medonic M-Series Hematology calibration records, the Medonic M-Series Procedure Manuals, and an interview with Testing Personnel 1 (TP1), the laboratory failed to perform calibration at least every six months, as required by the manufacturer. There was no record of one of two calibrations due in 2024. The findings include: 1. A review of the Hematology calibration records revealed the Medonic M-Series had no evidence of calibration the second half of 2024. 2. A review of the Medonic M- Series manual and the Quick Reference Guide revealed instructions specifying calibrations should be performed every six months. 3. The TP1 confirmed the above findings during the exit conference on 09-16-2025 at 3: 07 PM.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) 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 a review of personnel evaluation records and an interview with Testing Personnel 1 (TP1), the TC failed to assess and document the 2024 semi-annual competency for two of the seven Testing Personnel (TP) responsible for moderate complexity testing. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TC failed to perform and document the semi-annual 2024 competency assessments for TP2 and TP4 in 2024. 2. A further review of personnel records revealed the following: A) Training for TP2 was performed on 07-15-2023 with annual competency evaluations on 07-01-2024 and 07-01-2025. There was no evidence of a semi-annual evaluation performed by the TC during the first year of patient testing. B) Training for TP4 was performed on 07-15-2023 with annual competency evaluations on 07-15-2024 and 07-01-2025. There was no evidence of a semi-annual evaluation performed by the TC during the first year of patient testing. 2. During the exit conference on 09-16-2025 at 3:07 PM, TP1 confirmed the above findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on a review of personnel evaluation records and an interview with the Testing Personnel 1 (TP1), the TC failed to assess and document the 2025 annual competency

for one of the seven Testing Personnel (TP) responsible for moderate complexity testing. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TC failed to perform and document the annual competency assessment for TP7 in April 2025. 2. During the exit conference on 09-16-2025 at 3:07 PM, TP1 confirmed the above findings.