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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D0862701 | (X3) Date Survey Completed 07/22/2025 |
| Name of Provider or Supplier Afterhours Clinic Inc | Street Address, City, State 1800 Birmingham Ave, Jasper, 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 |
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| 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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, Medonic user manual, and an interview with Testing Personnel #1, the Laboratory failed to perform calibrations on the Medonic Hematology analyzer every six months as per manufacturer's requirements. This was noted for one of two possible calibrations reviewed in 2023 through 2024. The findings include: 1. A review of the Hematology calibration records revealed the Medonic was calibrated 7/19/2023 and then ten months later on 5 /1/2024. There was no evidence of documentation to review for the first half of 2024. 2. A further review of the Medonic user manual page 59 revealed, "Section 7: Calibration... It is recommended to calibrate the instrument every 6 months." 3. During an interview on 7/22/2025, at 11:56 AM, Testing Personnel #1 confirmed the calibration due in January 2024 was not performed.</p> |
| D5481 | <p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> |

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the 2024 Hematology Quality Control (QC) records for the Medonic Hematology analyzer, the patient results log, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of QC were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted for 1 day out of 31 days reviewed in May 2024. The findings include: 1. A review of the QC records for the Medonic Hematology analyzer revealed on 5/19/2024 both Low and High levels of QC records were not acceptable. 2. A review of the cumulative patient log printed from the instrument revealed 70 patient CBCs (Complete Blood Count) were performed on 5/19/2024. 3. During an interview on 7/22/2025 at 11:39 AM, Testing Personnel #1 confirmed QC was out for both Low and High control on 5/19/2024.