

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1074961	<b>(X3) Date Survey Completed</b>  04/07/2026
<b>Name of Provider or Supplier</b>  Urgent Care Northwest	<b>Street Address, City, State</b>  2708 Highway 78 East, Jasper, AL	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Clinical Coordinator (CC), the Laboratory Director (or designee) failed to sign the PT attestation statements for the specialty in Hematology. This was noted for two of six events reviewed in 2024 through 2026. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2025 Hematology 3rd Event (M3), b) 2026 Hematology 1st Event (M1). 2. During an interview on 4-7-26, at 1:13 PM, the CC confirmed the above findings.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology Quality Control (QC) records, and an interview with the Clinical Coordinator (CC), the laboratory used expired QC reagent on the Medonic Hematology analyzer. The surveyor noted the laboratory utilized expired QC</p>

	<p>for one day of patient testing in January 2026. The findings include: 1. A review of the Hematology QC records revealed the QC performed on 1/13/2026 expired prior to patient testing. 2. During an interview on 4-7-26, at 2:15 PM, the CC confirmed the above findings.</p>
<p><b>D5437</b></p>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 and an interview with Testing Personnel #2, the Laboratory failed to perform calibrations on the Medonic Hematology analyzer every six months as per the interview with TP#2. The laboratory failed to perform one of one calibration due in 2026. The findings include: 1. A review of the Hematology calibration records revealed the Medonic was last calibrated on 7/31/2025. There was no documentation of a calibration performed the first half of 2026. 2. During an interview on 4-7-26, at 2:17 PM, Testing Personnel #2 confirmed the calibration is performed every 6 months and the calibration due in January 2026 was not performed.</p>
<p><b>D5481</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology Quality Control (QC) records, patient log, and an interview with the Clinical Coordinator (CC), the Laboratory failed to ensure the Medonic Hematology QC was within the manufacturer's acceptable ranges prior to patient testing. This was noted for 3 days of 8 months reviewed in 2024 through 2026. The findings include: 1. A review of the QC records for the Medonic Hematology analyzer revealed the following: a) 7-22-25 all 3 levels of QC were not acceptable; 13 patients were performed, b) 7-24-25 all 3 levels of QC were not acceptable; 16 patients were performed, c) 7-29-25 QC levels 2 and 3 were not acceptable; 10 patients were performed. 2. During an interview on 4-7-26 at 2:15 PM, the CC confirmed QC was out for those 3 days.</p>
<p><b>D5781</b></p>	<p><b>CORRECTIVE ACTIONS</b></p>

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of the freezer temperature records, a review of the Triage Cardiac QC (Quality Control) package insert, and an interview with the Clinical Coordinator (CC), the Laboratory failed to implement and document corrective actions when the freezer temperature was outside the manufacturer's acceptable ranges for items stored therein. The surveyor noted freezer temperatures were above acceptable ranges for 9 of 16 months reviewed in 2025 through 2026. The findings include: 1. A review of the temperature records for the freezer where Triage Cardiac QC was stored revealed no documentation of corrective action for days when temperatures were below the acceptable ranges specified on the log (-20 Celsius or below), as follows: a) June 2025; 4 days -17C, b) July - December 2025 -17C, c) January - March -17C. 2. A review of the Triage QC package insert revealed, "Stored at -20 Celsius or below." 3. During an interview on 4-7-26, at 12:44 PM, the CC confirmed the above findings.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on reviews of the proficiency testing (PT) records, quality control (QC) records, calibration records, temperature records and testing personnel competencies, the Technical Consultant failed to provide adequate technical and scientific oversight of the laboratory. The findings include: 1. A review of the laboratory records revealed the Technical Consultant failed to: a) Sign the PT attestation statements for the specialty in Hematology (Refer to D2009). b) Ensure QC reagent was not expired on the Medonic Hematology analyzer prior to patient testing (Refer to D5417). c) Perform calibrations on the Medonic Hematology analyzer every six months as per the interview with TP#2 (Refer to D5437). d) Ensure the Medonic Hematology QC was within the manufacturer's acceptable ranges prior to patient testing. (Refer to D5481). e) Implement and document corrective actions when the freezer temperature was outside the manufacturer's acceptable ranges for items stored therein (Refer to D5781). f) Evaluate semi-annual competencies for testing personnel (TP) performing moderate complexity testing (Refer to D6053). g) Evaluate annual competencies for testing personnel (TP) performing moderate complexity testing (Refer to D6054).

**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 the personnel records and an interview with the Clinical Coordinator (CC), the Technical Consultant (TC) failed to evaluate semi-annual competencies for testing personnel (TP) performing moderate complexity testing. This was noted for one of one new TP listed on the CMS-209 (Laboratory Personnel Report) for 2026. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by either TC or the LD for the semi-annual competency of TP#1. 2. During an interview on 4-7-26, at 12:44 PM, the CC 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 the personnel records and an interview with the Clinical Coordinator (CC), the Technical Consultant (TC) failed to evaluate annual competencies for testing personnel (TP) performing moderate complexity testing. This was noted for one of one TP listed on the CMS-209 (Laboratory Personnel Report) for 2026. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by either TC or the LD for the annual competency of TP#2. 2. During an interview on 4-7-26, at 12:44 PM, the CC confirmed the above findings.