Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1047702	03/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mana Urgent Care Wedington	1188 Salem Road, Suite 6, Fayetteville, AR	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon a review of policy and procedure, lack of documentation, and interview with laboratory staff it was determined that the laboratory failed to have procedures for QC and corrective action to take when QC results fail to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's policy and procedure manual revealed there was no policy for the type and identity of controls, number and frequency of QC performence, or the criteria to determine acceptable QC results in the manual. B) Upon request, the laboratory could not provide policies and

	procedures that defined unacceptable quality control results and corrective actions to take in the event of control failures. C) In an interview on March 19, 2025, at 2:43 p. m. the laboratory staff member (# 3 on form CMS 209) verified that policies and procedures defining acceptable/unacceptable quality control results and corrective actions to follow in the event of unacceptable quality control results were not available.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Laboratory Policy and Procedure Manual and interviews with laboratory staff, the laboratory director failed to approve, sign, and date the changes to the policy and procedures for "I-Stat Value Assigment Sheet" and "Specimen Rejection". Survey findings include: A) Review of the policy and procedure "I-Stat Value Assignment Sheet: revealed hand-written changes were made without the date or the identity of the person making the change noted.on the policy and procedure and, the policy "Specimen Rejection" listed multiple criteria for specimen rejection and criteria numbers 2 and 5 were crossed out by hand without the date or identity of the person making the change noted on the policy and procedure. B) In an interview at 3:20 p.m. on 3/19/25, laboratory staff member (#2 as listed on the form CMS-209) confirmed hand-written changes were made to the policy and procedure manual and it could not be determined who made the changes and if the laboratory director approved the changes.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based upon interview with laboratory staff members, complete blood cell count (CBC) Quality Control (QC) reports, patient result reports, and lack of documentation the laboratory reported patient CBC result without performing required quality control on two of twenty-nine days of testing in March 2024. Findings follow: A) In an interview on 3/19/25 at 02:00 p.m. the laboratory staff member (# 3 on form CMS 209) stated that "Hematology (low, normal, high) are performed on each day of patient testing and all levels must be within established acceptable range before reporting patient results. B) Review of CBC QC report for March 2024 revealed that there was no evidence of QC being performed on Monday 3/4/24 or Sunday, 3/17/24.

	C) Review of patient results reports revealed that CBC's were performed and reported on patients 1389883, 700357410, 329227 on Monday, 3/4/24 and a CBC was performed and reported on patient 1139728 pn Sunday 3/17/24 D) Upon request, the laboratory was not able to provide the documentation of QC results for CBC testing on 3/4/24 and 3/17/24 E) In an interview on 3/19/25 at 3:15 p.m. the laboratory staff member (identified as number 3 on form CMS 209) confirmed that CBC's were performed and reported on those days, identified above, without the required quality control being perfomed.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based upon a review of complete blood cell count (CBC) quality control (QC) results, lack of documentation, and interview with laboratory staff members, the laboratory did not document corrective action when QC results for CBC testing failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of QC for CBC testing revealed that hemoglobin (hgb) High control , lot # 089000 with an acceptable range of (16.4 to 18.2) was recorded as below 16.4 on 10 successive occasions between 9:57 a.m. and 12:40 p.m. on 3/12/24. B) Upon request, the laboratory was unable to provide documentation of the corrective action taken to achieve acceptable results for QC for hgb High control on the date identified above. Multiple attempts taken to achieve acceptable results is not corrective action. C) Review of QC for CBC testing revealed that Red Blood Cell Count (RBC) Low control , lot # 352416511 with an acceptable range of (2.19 to 2.49) was recorded as below 2.19 on ten successive occasions on 10/21/24 between 07:02 a.m. and 09:51 a.m. D) Upon request, the laboratory was unable to provide documentation of the corrective action taken to achieve acceptable results for QC for RBC Low control on 10/21/24. Multiple attempts taken to achieve acceptable results is not corrective action. E) In an interview on 3/19/25 at 3:40 p.m., the laboratory staff member (# 3 on form CMS 209) confirmed that corrective action taken was not documented on the instances identified above.