| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>04D1047702 | (X3) Date Survey Completed<br>05/19/2021 |
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| **Name of Provider or Supplier**<br>Mana Urgent Care Wedington | **Street Address, City, State**<br>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 |
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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Through review of the manufactuer's package insert, observation and interview it was determined that the laboratory failed to note the amended expiration date or the date opened was not present for hematology control material. A) Review of the package insert for Coulter 4C hematology controls revealed that expiration date should be changed to ten days after the control material vials were opened and placed into use. B) During a tour of the laboratory on 5/19/21 at 02:30 PM three vials of Coulter 4C hematology controls lot numbers 069900, 079900, and 089900 were observed in the laboratory refrigerator without a date opened or amended expiration date. C) In an interview on 5/19/21 at 02:30 PM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the hematology control material, identified above, were currently in use and the date of opening or amended expiration date was not present on the control vials. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform |

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| | 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of laboratory personnel files, lack of documentation, and interviews with staff, it was determined the laboratory director failed to authorize personnel #8 through #14 (as listed on CMS-209) to perform testing without direct supervision. Survey findings follow: A. Surveyor reviewed personnel records of twelve personnel. Personnel #8 through #14 (as listed on CMS-209) did not include a signed authorization to perform moderate complexity testing by laboratory director. The authorizations to test were signed by the personnel, identified as number seven on the CMS 209 form who is not the laboratory director. B. In an interview at 02:30 PM on 5 /19/21, laboratory #2 (as listed on the form CMS-209) confirmed there were no written authorizations to perform testing signed by the laboratory director. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Through review of the laboratory's personnel records, the CMS 209 form, and interview it was determined that testing personnel competency evaluations for seven of twelve testing personnel were not performed by the technical consultant or personnel identified on the CMS 209 form with the qualifications of a technical consultant. Findings follows: A.) The CMS-209 form completed for the survey lists employee number two on the CMS 209 form as the laboratory's technical consultant. B) Review of fifteen competency evaluations for laboratory testing personnel identified as numbers eight through fourteen on the CMS 209 form revealed that they were evaluated and signed by the laboratory personnel, identified as a testing personnel number seven on the CMS 209 form C) Review of the personnel qualifications for testing personnel, identified as number seven on the CMS 209 form, revealed that the personnel lacked the required qualifications to serve as technical consultant. D) In an inteview on May 19, 2021 at 02:10 PM, the Laboratory Technical Consultant identified as number two on the CMS 209 form confirmed that the person identified as number seven on the CMS 209 form evaluated the competencies and signed the competency evaluations for the testing personnel identified as numbers eight through fourteen on the CMS 209 form. |