| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D1047702 | 10/11/2018 |
| **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 |
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| **D0000** | This reflects findings of a recertification survey performed on 10/11/18 . Mediserve Wedington Walk-In Clinic Laboratory is in compliance with the applicable Standards and conditions of 42 CFR Part 493, Laboratory Requirements. The following standard level deficiencies were cited on current survey: D2009: CFR 493.801(b) The laboratory director did not attest to the routine integration of proficiency testing samples into the patient workload in three of five events reviewed. D6032: CFR493. 1407(e)(14) The laboratory director did not sign an authorization to perform testing for two of eight testing personnel. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Through review of proficiency testing attestation forms, API proficiency testing instructions and interview with laboratory staff it was determined that the laboratory director did not attest that the proficiency testing was performed in the same manner as patient testing in three of five events reviewed. Survey findings follow: A. The instructions for API proficiency testing states, "signatures required: testing personnel and the laboratory director must physically sign an attestation statement for all proficiency testing results". B. API proficiency testing Hematology/Coagulation first event 2017, lacked signature of the laboratory director attesting that testing was performed in the same manner as patient testing . C. API proficiency testing Hematology/Coagulation second event 2017, lacked signature of the laboratory director attesting that testing was performed in the same manner as patient testing . D. API proficiency testing Hematology/Coagulation first event 2018, lacked signature of the laboratory director attesting that testing was performed in the same manner as |

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| | patient testing . E. In an interview at 10:45 AM on 10/11/18, the technical consultant identified as number two on the CMS 209 form confirmed that the laboratory director's signature was not present on the API proficiency testing Hematology /Coagulation testing events identified above. |
| **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 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 review of the CMS 116 form supplied by the laboratory, the CMS 209 form supplied by the laboratory, personnel files and lack of documentation it was determined that two of eight testing personnel performed testing without the written authoritization of the Laboratory Director. Findings follow: A. The CMS 116 form stated that 2394 moderately complex hematology tests were performed. B. The testing personnel identified as number eight and number ten on the CMS 209 form were identified as testing personnel performing hematology testing. C. Review of the personnel files for testing personnel identified as number eight and number ten on the CMS 209 form did not include written authorization by the laboratory director to perform hematology testing. D. Upon request, the laboratory was unable to provide an authorization to test, signed by the laboratory director, for the personnel identified above. E. In an interview on 10/11/18 at approximately 11:00 AM the technical consultant identified as number two on the CMS 209 form confirmed that the personnel identified above performed hematology testing and lacked an authorization to test signed by the laboratory director. |