| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 24D0402137 | 03/12/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| M Health Fairview Clinic - Edina | 6545 France Avenue South, Edina, MN | |

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** | Validation survey A validation survey was performed on March 12, 2026, with the following standard level deficiency cited. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's urinalysis procedure, direct observation, reference material provided by the laboratory, interview with the testing personnel #5 and Lab Laboratory Director, the laboratory failed to define in their procedure the exact time and centrifugation speed parameters for preparation of urine sediment testing for |

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| | microscopic urines for the last two years as evidenced by: 1. The laboratory's urinalysis procedures stated, "Each centrifuge will be evaluated and list RPM, g Force (RCF) and spin time. General centrifuge guidelines: 5 minutes at (1500-1800 rpms), 3 minutes at (2000-3000 rpms), 2 minutes at >1300 RCF (>3000 rpms)." This procedure stated time and speed for centrifuge "evaluation" The laboratory's procedure failed to define specific time and speed for urine sediment preparation. 2. In direct observation at 1046, The laboratory programmed the centrifuge used for urine sediment preparation bench centrifuge 6F serial #22113JL814 at 3371 RPMs for 2 minutes (1652 RCFs). 3. In interview with testing person #5 at 1217, she confirmed that the centrifuge setting and was not sure certain of the origins of the settings. 4.The laboratory was asked to provide sources referenced in the procedure. The laboratory could only provide the following reference: Urinalysis and Body Fluids, Strasinger, Di Lorenzo fifth edition. The reference stated chapter 6 pg. 83 under centrifugation, "Centrifugation for 5 minutes at a relative centrifugal force (RCF) of 400 produces optimum amount of sediment with the least chance of damaging the elements." 5. In interview with Laboratory Director at 1217 confirmed that they didn't have any of the references listed in the procedures onsite and could only provide the above Urinalysis book. She did know know where the settings came from. 6. The laboratory performed 279 microscopic urines in December 2025. |