

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0402212	<b>(X3) Date Survey Completed</b>  09/11/2025
<b>Name of Provider or Supplier</b>  M Health Fairview Clinic - Oxboro	<b>Street Address, City, State</b>  600 W 98th St, Bloomington, MN	
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>D0000</b>	<p>. The M Health Fairview Clinic - Oxboro laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed on September 11, 2025. The following standard-level deficiencies were cited: 493.1252 Test systems, equipment, instruments, reagents, materials, and supplies 493.1281 Comparison of test results .</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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure blood collection tubes were not used after the expiration date had been exceeded in September 2025. Findings are as follows: 1. The laboratory performed Coagulation testing under the Hematology specialty as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 10:04 a. m. on 9/11/25. 2. Two expired sodium citrate blood collection tubes were observed as present and available for use in one of two draw stations evaluated during the tour. See below. Lot # 5048247 Expiration 08/31/2025 3. The laboratory performed the following Coagulation tests using sodium citrate blood collection tubes as indicated on the Form CMS-116 provided by the laboratory on the date of survey: Prothrombin Time (PT) Partial Thromboplastin Time (PTT) D-Dimer 4. The laboratory checked supply for expiration dates semi-annually as indicated on the Clinics Quality Assurance Review logs found in the laboratory's quality assurance documentation. 5. In an interview at 10:19 a.m. the TS confirmed the above findings and indicated 338 Coagulation tests had been performed in September 2025. .</p>

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with the laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from two identical Toxicology test systems at least twice annually in 2024 and 2025. Findings are as follows: 1. The laboratory performed Toxicology testing under the Chemistry specialty as indicated on the form CMS-116 provided by the laboratory on the date of survey. 2. Two identical MedTox Profile V test systems were observed as present and available for use for urine drugs of abuse testing during the tour. 3. A procedure for twice annual comparison of duplicate test systems was not established in the laboratory's policy manual found in Media Lab. 4. Documentation of test system comparison was not found during a review of the laboratory records from 2024 and 2025. The laboratory was unable to provide this documentation upon request. 5. In an interview at 11:43 a.m. on 9/11/25, the Technical Supervisor confirmed the laboratory does not currently compare the two identical MedTox Profile V test systems and indicated the lab performed 553 urine drugs of abuse tests in 2024 and 482 urine drugs of abuse tests in 2025 on the MedTox Profile V test systems. .