Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2329582	03/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Midwest Men's Health	1700 Highway 36 West, Suite 790, Roseville, 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
D0000	The Midwest Men's Health DBA GameDay Men's Health 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 initial certification survey performed on March 4, 2026. The following standard-level deficiencies were cited: 493.1241 Test request 493.1252 Test systems, equipment, instruments, reagents, materials, and supplies 493.1407 Laboratory director responsibilities .
D5301	TEST REQUEST CFR(s): 493.1241(a) (a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to utilize a written or electronic test request for all testing completed from date of implementation, 10/23/25, through date of survey, 03/04/26. Findings are as follows: 1. The laboratory performed Testosterone (TEST) and Prostrate-Specific Antigen (PSA) testing as indicated by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 03/04/26. 2. A NanoEntek FREND System was observed as present and available for use during the tour. The laboratory began testing patient specimens using this test system on 10/23/25. 3. Providers verbally requested TEST and PSA for patient specimen testing and TP1 entered the order into Lobbie, the laboratory's electronic medical record, as indicated by TP1 during the tour. TP1 stated the providers did not provide written test request documentation within 30 days of the verbal request. 4. The Specimen Collection and Handling procedure, found in the laboratory's procedure software MediaLab, indicated documentation accompanied each specimen to the laboratory and was used for specimen verification. 5. Test request documentation was not found for four of four patient test results from October 2025 through February 2026 reviewed on date

	of survey. The laboratory was unable to provide test request documentation upon request. 6. In an interview at 2:30 p.m. on 03/04/26, the Technical Consultant (TC) confirmed the above finding and indicated providers should have entered test requests into Lobbie. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure specimen collection tubes were not used after the expiration had been exceeded in 2026. Findings are as follow: 1. The laboratory performed Testosterone (TEST) and Prostrate-Specific Antigen (PSA) testing as indicated by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 03/04/26. 2. A NanoEntek FREND System was observed as present and available for use during the tour. Lithium Heparin collection tubes were used for TEST and PSA testing using this system. 3. Sixteen expired Vacuette LH Lithium Heparin Sep Tubes with lot number C4111367 and expiration date 01/31/26 were observed as present and available for use in the blood collection room during the tour. Non-expired BP Vacutainer Lithium Heparin tubes were also observed in the collection room. 4. Thirty one patients received TEST and/or PSA testing between 02/01/26 through 03/04/26 as indicated by TP1 and confirmed via the laboratory's patient testing log. TP1 was unable to determine how many expired collection tubes had been used for testing. 5. A policy prohibiting the use of expired supplies was not found during review of the laboratory's written policies and procedures found in Media Lab, the laboratory's procedure software. 6. In an interview at 10:25 a.m. on 03/04/26, TP1 confirmed the above findings. .
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director (LD) failed to perform a site visit in 2025. Findings are as follows: 1. The laboratory performed Testosterone and Prostrate-Specific Antigen testing as indicated by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:05 a.m. on 03/04/26. 2. A NanoEntek FREND System was observed as present and available for use during the tour. The laboratory began testing patient specimens using this test system on 10/23/25. 3. Documentation of an LD site visit was not found during review of 2025 laboratory records and documents. 4. A policy establishing the

	frequency, content, and documentation of required LD site visits was not found during review of the laboratory's written policies and procedures found in Media Lab, the laboratory's procedure software. 5. In an interview at 2:15 p.m. on 03/04/26, TP1 confirmed the above finding and indicated the LD had not performed a site visit in 2025.