Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 24D2072541	**(X3) Date Survey Completed** 02/04/2025
Name of Provider or Supplier Valley Medical And Wellness	**Street Address, City, State** 2438 East 117th Street, Burnsville, 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 Valley Medical and Wellness 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 recertification survey performed on January 31, 2025. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance 493.1281 Comparison of test results .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to verify the accuracy of two non-regulated Chemistry analytes at least twice annually in 2023 and 2024. Findings are as follows: 1. The laboratory performed high complexity Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory at 10:05 AM on 1/31/2025. 2. Three Shimadzu 8060NX LC/MS instruments were observed as present and available for use during the tour. The laboratory performed a pain panel including the following non-regulated analytes: Xylazine p-OH-Xylazine 3. Shimadzu 8060NX LC/MS accuracy verification was required twice annually for non-regulated analytes as established within the GEN SOP Proficiency Testing Policy found in MediaLab software. 4. Accuracy of Xylazine and p-OH-Xylazine testing was verified once in 2023 as found in the CAP Proficiency Testing binder. No other verification documentation was found for these analytes in 2023. No verification documentation was found for Xylazine and p-OH-Xylazine in 2024. 5. The laboratory was unable to provide the missing verification of accuracy documentation upon request. 6. The laboratory

	performed approximately 414,00 Toxicology tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 7. In an interview at 4:30 PM on 1/31/25, GS1 confirmed the above finding. .
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, record review, and an interview with laboratory personnel, the laboratory failed to document the evaluation of the relationship of test results between three Chemistry instruments at least twice annually in 2023 and 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory at 10:05 AM on 1/31/2025. 2. Three Shimadzu 8060NX LC/MS instruments were observed as present and available for use for Toxicology testing during the tour. 3. A twice-annual process for comparison of test results obtained from different instruments was found in the laboratory's Performing 6-month Instrument Comparability Studies for Analytical Test Systems procedure found in the MediaLab software. 4. Test result comparison documentation for the three Shimadzu 8060NX LC/MS instruments was not found for 2023 and 2024. 5. In a telephone interview with Testing Personnel 16 (TP16), GS1, and the Laboratory Director at 9:03 AM on 2/4/25, TP16 confirmed the test comparisons between the three Shimadzu 8060NX LC/MS instruments had been completed but not documented in 2023 and 2024. .