

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2286988	(X3) Date Survey Completed 08/28/2025
Name of Provider or Supplier Parity Wellness	Street Address, City, State 2002 Suburban Ave, Saint Paul, 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	<p>. The Parity 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 validation survey performed on August 28, 2025. The following standard-level deficiency was cited: 493.1236 Evaluation of proficiency testing performance .</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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 one of nine non-regulated Chemistry analytes in 2024 and 2025. Findings are as follows: 1. The laboratory performed a nine-analyte Toxicology panel as confirmed by Testing Personnel 1 during a tour of the laboratory at 10:05 a.m. on 08/28/2025. 2. A Thermo Fisher Indiko Plus analyzer was observed as present and available for use during the tour. The laboratory began testing the Toxicology panel, which included the non-regulated analyte Phencyclidine, in August 2024. 3. Proficiency testing of all analytes was required as established in the Proficiency Testing and Employee Competency procedure found in the Laboratory General and Toxicology Procedures manual. 4. The laboratory performed proficiency testing using the the American Proficiency Testing (API) provider. 5. Phencyclidine was not included in the API 2024 Chemistry Miscellaneous 2nd event nor in the API 2025 Chemistry Miscellaneous 1st event as indicated in the API performance evaluation reports from those events. 6. The laboratory performed approximately 19,200 Toxicology tests annually as indicated on the Form CMS-116 Clinical</p>

Laboratory Improvement Amendments (CLIA) Application for Certification provided by the laboratory on date of survey. 7. In an interview at 11:10 a.m. on 08/28/25, the Laboratory Consultant confirmed the above finding. .