

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2145552	<b>(X3) Date Survey Completed</b>  05/05/2026
<b>Name of Provider or Supplier</b>  Simplicity Health	<b>Street Address, City, State</b>  3260 42nd Ave S, Saint Cloud, 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>	The Simplicity 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 recertification survey performed on May 5, 2026. The following standard-level deficiency was cited: 493.1236 Evaluation of proficiency testing performance .
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:  . Based on document review and interview with laboratory personnel, the laboratory failed to investigate two unacceptable Chemistry proficiency testing (PT) results out of thirty challenges completed in 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 11:15 a.m. on 05/05/26. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The laboratory received one unacceptable Carbon Dioxide (CO2) PT result of fifteen testing challenges completed in 2025 and one unacceptable 25-OH Vitamin D (VitD) PT result of fifteen testing challenges completed in 2025 as indicated in the API 2025 Chemistry - Core - 3rd Event Comparative Evaluation report. See below. 2025 - 3rd Chemistry Core Event Test: CO2 Sample: CH-11 Laboratory result: 16 API expected result: 18-28 Test: VitD Sample: IAS-13 Laboratory result: &gt;120 API expected result: 92-111 4. Unacceptable PT result investigation was required as established in the laboratory's Proficiency Testing procedure found in the General Lab Policies manual. 5. Investigation documentation for the unacceptable CO2 and VitD scores was not found during review of laboratory PT records. The laboratory was unable to provide investigation and corrective action records for these unacceptable PT results upon</p>

request. 6. In an interview at 12:45 p.m. on 05/05/26, the LD confirmed the above finding. .