

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2298638	(X3) Date Survey Completed 09/16/2025
Name of Provider or Supplier Allina Health Lakeville Specialty Center	Street Address, City, State 18465 Orchard Trail, Lakeville, 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 Allina Health Lakeville Specialty Center 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 16, 2025. The following standard-level deficiency was cited: 493.1407 Laboratory director responsibilities .</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for testing performed using the i-STAT analyzer in 2024. Findings are as follows: 1. The laboratory performed Basic Metabolic Panel testing using a Chem 8+ cartridge on the i-Stat analyzer as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 09/16/25. 2. An i-STAT analyzer and Chem 8+ cartridges were observed as present and available for use during the tour. The laboratory began Chem 8+ panel testing on the i-STAT on 08/13/24 as indicated by TC1. The following analytes were included in the Chen 8+ cartridge: Sodium Potassium Chloride TCO2 Anion Gap* Ionized Calcium Glucose Urea Nitrogen Creatinine Hematocrit Hemoglobin* * Calculated 3. The laboratory performed proficiency testing (PT) using the the American Proficiency Testing (API) provider. 4. PT documentation for the above analytes was not found during review of the laboratory's 2024 API PT records. The laboratory was unable to provide PT records or alternative verification of accuracy records for Chem 8+ panel testing completed in 2024 upon request. 5. The laboratory was enrolled in and performed PT for Chem 8+ panel testing in 2025 as verified by the laboratory's 2025 API PT</p>

records. 6. In an interview at 12:10 p.m. on 09/16/25, TC1 confirmed the above finding. TC1 and TC4 indicated the laboratory performed 240 Chem 8+ panels in 2024. .