Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404521	06/25/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mayo Clinic Labs - Kasson Clinic	411 West Main Street, Kasson, 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 Mayo Clinic Labs- Kasson Clinic 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 June 25, 2026. The following standard-level deficiencies were cited: 493.1281 Comparison of test results .
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, document review, and interview with laboratory personnel, the laboratory failed to evaluate and document the relationship between two non-waived Coagulation testing methods in 2024 and 2025. Additionally, the laboratory failed to evaluate and document the relationship between two identical Coagulation testing devices at least twice annually in 2024 and 2025. Findings are as follows: 1. The laboratory performed Coagulation testing under the Hematology specialty as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:35 a. m. on 6/25/26. 2. The following Coagulation testing methods for International Normalized Ratio (INR) testing were observed as present and available for use during the tour: Werfen IL ACL Top 300 CTS coagulation analyzer Two Coaguchek point of care devices 3. The laboratory was required to compare duplicate non-waived testing methods and identical testing devices twice annually as defined in the Comparability of Instruments/Methods Procedure provided by the laboratory on the date of survey. 4. Comparison documentation for the two Coaguchek devices was not found during review of laboratory records. Additionally, comparison documentation between the

	ACL Top 300 and the Coaguchek devices was not found. The laboratory was unable to provide this documentation upon request. 5. In an interview at 2:06 p.m., the GS confirmed the above findings and indicated the laboratory performed the following tests on patient samples: Year Coagucheks IL ACL Top 300 CTS 2024 2,236 482 2025 2,280 463 .