

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404769	(X3) Date Survey Completed 06/30/2026
Name of Provider or Supplier Mankato Clinic	Street Address, City, State 1230 East Main Street, Mankato, 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 Mankato 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 recertification survey performed on June 29-30, 2026. The following standard-level deficiencies were cited: 493.1291 Test report .
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of two pertinent Coagulation reference intervals were included on a patient test report from 2025. Findings are as follows: 1. A Siemens CA-660 Coagulation analyzer was observed as present and available for use for Prothrombin Time (PT) testing on patient samples under the Coagulation subspecialty as confirmed by the General Supervisor (GS) during a tour of the laboratory at 11:53 a.m. on 6/29/26. 2. A reference interval for PT was not included on a patient test report from 7/31/25 reviewed on the date of survey. See below: Patient Test Report from 7/31/25 Analyte Reference Range Prottime ----- INR 0.83 - 1.19 sec 3. The reference interval established for the PT reagent lot in use at the time of patient testing was defined in the CA-660 Innovin Prottime policy found in the CA-660 Procedure Manual. See below. Lot # 564674 Dates in Use 4/1/25 - 4/10/26 Reference interval 8.5 - 11.7 sec 4. In an interview at 12:42 p.m. on 6/30/26, the GS confirmed the above findings and indicated the laboratory performed 1,011 PT tests on patient samples while lot 564674 was in use. .