

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0662972	<b>(X3) Date Survey Completed</b>  09/18/2025
<b>Name of Provider or Supplier</b>  Mapleton Family Medicine Clinic	<b>Street Address, City, State</b>  305 Main St Ne, Mapleton, 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 Mapleton Family Medicine 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 September 18, 2025. The following standard-level deficiencies were cited: 493.1413 Technical consultant responsibilities .
<b>D6047</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure documented observation of test performance was completed for all test systems in the laboratory in 2023 and 2024 for two of two Testing Personnel (TP) during annual competency assessments. Findings are as follows: 1. The laboratory performed Hematology, Chemistry, and Microbiology testing as confirmed by the TC during a tour of the laboratory at 12:04 p.m. on 9/18/25. The following test systems were observed as present and available for use during the tour: Hematology: Sysmex DxH520 Chemistry: Beckman Icon Serum HCG test kit Microscopic Urinalysis: Nikon Eclipse E200 2. The laboratory was required to document direct observation of test performance for all moderate-complexity test systems as indicated in the competency assessment criteria included in the Mankato Clinic Satellite Laboratory Orientation and Competency Checklist found in the Quality Assurance binder provided by the laboratory on the date of survey. 3. Documentation of direct observation of the following tests was missing from completed 2023 and 2024 competency assessments for TP1 and TP2. CBC (complete blood count) Serum HCG Microscopic Urinalysis 4. The laboratory performed 109 microscopic urinalysis tests, 5 serum HCG tests, and 6,048 CBC's annually as</p>

indicated on the form CMS-116 provided by the laboratory on the date of survey. 5. In an interview at 1:11 p.m. the TC confirmed the above findings. .

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(vi)

(b)(8)(vi) Assessment of problem-solving skills; and

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure documented evaluation of problem solving skills was completed during 2023 and 2024 competency assessments for two of two testing personnel (TP). Findings are as follows: 1. The laboratory performed serum HCG (human chorionic gonadotropin) testing under the Chemistry specialty as confirmed by they TC during a tour of the laboratory at 12:04 p.m. on 9/18/25. 2. A Beckman Icon serum HCG test kit was observed as present and available for use during the tour. 3. The laboratory was required to evaluate problem solving skills annually for each test system as indicated on the Mankato Clinic Satellite Laboratory Orientation and Competency Checklist found in the Quality Assurance binder provided by the laboratory on the date of survey. 4. Evaluation of problem solving skills for serum HCG testing was not included on annual competency assessments for TP1 and TP1 in 2023 and 2024. 5. The laboratory performed 5 serum HCG tests annually as indicated on the form CMS-116 provided by the laboratory on the date of survey. 6. In an interview at 1:11 p.m. the TC confirmed the above findings. .