

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404769	(X3) Date Survey Completed 10/15/2020
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
D5211	<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 an unacceptable Chemistry proficiency testing (PT) result for 1 analyte in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 8:15 a.m. on 10/15/20. 2. The laboratory performed PT using the College of American Pathologists (CAP) program. 3. The laboratory received an unacceptable Calcium (CA) PT result in the CAP C-A 2020 General Chemistry/Therapeutic Drugs event. See below. Sample Test Lab result CAP range CHM-01 CA 13.80 11.77-13.78 4. Investigation of unacceptable PT results was required as established in the Evaluation of Proficiency Results procedure located in the laboratory's Quality Assurance manual. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12:15 p.m. on 10/15 /20, TS1 confirmed the above finding. .</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure a solution used for Immunohematology testing was not used after the expiration date had been exceeded in 2019. Findings are as follows: 1. The laboratory performed ABO/Rh Immunohematology testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 8:15 a.m. on 10/15/20. 2. Expired MTS Diluent 2 Plus was used for testing patient specimens in December 2019 as indicated on the Blood Bank Daily Checks log provided by the laboratory. See below for detailed information. Solution - MTS Diluent 2 Plus Lot - MDP170 Expiration date - 12/10/19 Date of use Patients tested 12/11/19 7 12/12/19 6 12/13/19 4 3. In an interview at 3:50 p.m. on 10/15/20, TS1 confirmed the above finding.