

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0673484	(X3) Date Survey Completed 05/10/2023
Name of Provider or Supplier Morgan Medical Clinic	Street Address, City, State 96 3rd Street, Morgan, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure hematology proficiency testing samples from one of three 2021 PT events were tested consistent with the number of times the laboratory routinely tested patient specimens Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on May 10, 2023 at 10:00 a.m. An Sysmex XN430 hematology analyzer was observed as present and available for use during the tour. 2. The laboratory performed proficiency testing (PT) for Hematology using the American Proficiency Institute (API) proficiency testing provider in 2021. 3. Hematology PT samples XE-06 through XE-101 from the API 2021 Hematology/Coagulation 2nd Event were tested on two time as indicated on test result documents generated by the Sysmex XN430 analyzer. See below for times of the first and second tests performed. Sample 1st run 2nd run XE-06 12:31 12:35 XE-07 12:37 12:48 XE-08 12:39 12:50 XE-09 12:41 12:52 XE-10 12:43 12:54 4. In an interview at 11:20 a.m. on May 10, 2023, Testing Personnel 1 confirmed the above findings. .</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between a Chemistry procedure and a final patient test report. The laboratory performs approximately 804 routine chemistry tests per year. Findings are as follows: 1. The laboratory performed the iSTAT Chem 8+panel which falls under the specialty of Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:00 a.m. on May 10, 2023. 2. An Abbott iSTAT handheld blood analyzer, which the Chem 8+ panel is performed on, was observed as present and available for use during the tour of the laboratory. 3. The reference intervals for 6 of 8 analytes listed in the iSTAT Analyzer procedure located in the Laboratory Procedure manual, was not consistent with that included on the test report for patient MXXXXXX412, tested on 03/01/23, reviewed on date of survey, 5/10/23. See below Analyte Procedure Report Sodium 138-146 mmol/L 134-144 mmol/L Potassium 3.5-4.9 mmol/L 3.5-5.2 mmol/l Chloride 98-109 mmol/L 98-113 mmol/L BUN 8-26 mg/dL 7-23 mg/dL Glucose 70-105 mg/dL 70-110 mg/dL Creatinine 0.6-1.3 mg/dL 0.1-1.3 mg/dL 4. In an interview at 11:35 a.m. on May 10, 2023, the GS confirmed the above findings. .