

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0935418	<b>(X3) Date Survey Completed</b> 03/27/2019
<b>Name of Provider or Supplier</b> Lake Region Healthcare Morris Medical Center	<b>Street Address, City, State</b> 24 E 7th St, Morris, 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>D5211</b>	<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 unacceptable Chemistry proficiency testing (PT) results for 2 analytes in 2017. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/27/19 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received an unacceptable PT result from API for the survey event, sample and analytes listed below. Survey Event: 2017 Chemistry Core / 2nd Sample: CM-10 Analytes: Myoglobin Troponin 4. An investigation of the unacceptable PT results were not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 5. In an interview on 03/27/19 at 12:30 p.m., TP1 confirmed the above findings. .</p>
<b>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory</p>

failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/27/19 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received non-graded Chemistry results from API for the event and tests listed below. The Data Summaries from API with the expected results for these tests were not included in laboratory records. Survey Event: 2017 Chemistry Core / 1st Sample: CH-01 Analytes: LDL Cholesterol (Calculated) Survey Event: 2018 Chemistry Core / 1st Sample: CH-02, CH-03 Analytes: LDL Cholesterol (Calculated) Survey Event: 2018 Chemistry Core / 3rd Sample: CH-11 Analytes: LDL Cholesterol (Calculated) 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 03/27/19 at 12:30 p.m., TP1 confirmed the above findings. .

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(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 reference intervals were consistent between a Hematology procedure and a patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/27/19 at 10:05 a.m. 2. An Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour. 3. Two reference intervals listed in the Reference Ranges - Morris Campus procedure & Hematology / Coagulation Reference Ranges table, both located in the Lab Manual - Morris Campus, were not consistent with those included on the patient test report (Date Performed = 1/31/18, Sex / Age = Female / 53 years) reviewed on date of survey, as indicated below. Analyte Table Report WBC\* 3.5 - 10.8 4.5 - 10.5 # MID\* 0.0 - 1.8 0 - 1 4. In an interview on 03/27/19 at 1:30 p.m., TP1 confirmed the above findings. \*Note WBC = White Blood Cell Count # MID = Absolute number of Mid-Sized WBC .