

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0651439	<b>(X3) Date Survey Completed</b>  07/02/2021
<b>Name of Provider or Supplier</b>  Lake View Memorial Hospital	<b>Street Address, City, State</b>  325 11th Ave, Two Harbors, 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>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from the Hematology analyzer and a manual testing method, and between two different Chemistry analyzers, at least twice annually. Findings are as follows: A. Hematology 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 7:05 a.m., on 07/01/21. 2. A Sysmex XL - 450 hematology analyzer was observed as present and available for use during the tour. The GS indicated the laboratory performed and reported both automated and manual White Blood Cell (WBC) differential testing. 3. The Sysmex XL - 450 / Complete Blood Count procedure, located in the on-line policy and procedure manual, did not include a requirement to compare WBC automated and manual differential testing twice annually. Twice annual comparisons of these test methods was not found in laboratory records. The laboratory was unable to provide comparison records upon request. 4. In an interview at 11:15 a.m., on 07/01/21, the GS confirmed the above finding. B. Chemistry 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 7:05 a.m., on 07/01/21. 2. A Siemens Healthineers Dimension EXL chemistry analyzer, and an Abbott i-STAT chemistry analyzer, were observed as present and available for use during the tour. The GS indicated the laboratory performed and reported basic metabolic chemistry panels (BMP) by both methods. 3.</p>

	<p>The i-STAT and Dimension EXL procedures, both located in the on-line policy and procedure manual, did not include a requirement to compare BMP testing twice annually. Twice annual comparisons of these test methods was not found in laboratory records. The laboratory was unable to provide comparison records upon request. 4. In an interview at 11:15 a.m., on 07/01/21, the GS confirmed the above finding. .</p>
<p><b>D5807</b></p>	<p><b>TEST REPORT</b> 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> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure a reference interval was consistent between a Chemistry procedure and a patient test report. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 7:05 a.m., on 07/01/21. 2. A Siemens Healthineers Dimension EXL chemistry analyzer was observed as present and available for use during the tour. 3. A reference interval listed in the Siemens Dimension EXL System Electrolytes (Na, K, Cl) procedure, located in the on-line policy and procedure manual, was not consistent with that included on a patient test report reviewed on date of survey, as indicated below. Patient - adult male, aged 86 yrs, tested on 8/04/20 Test: Chloride Procedure 96 - 107 mmol/L Report 98 - 107 mmol/L 4. In an interview at 2:45 p.m., on 7/01/21, the GS confirmed the above finding. .</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure 5 of 5 testing personnel were evaluated for test procedure competency in all specialties in 2019 and 2020. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 7:05 a.m., on 07/01/21. 2. A Vital Diagnostics Excyte Mini Erythrocyte Sedimentation Rate (ESR) analyzer was observed as present and available for use during the tour. 3. In an interview at 8:25 a.m., on 7/01/21, the GS confirmed that the laboratory performed Post Vasectomy Semen Analysis testing. 4. Competency assessments for the above test methods were not included in the Competency Evaluation procedure, or forms completed in 2019 and 2020 for 5 of 5 testing personnel. 5. The laboratory was unable to provide the missing evaluations upon request. 6. In an interview at 8:25 a.m. on 7/01/201, the GS confirmed the above finding.</p>