

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0651439	<b>(X3) Date Survey Completed</b> 01/11/2023
<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>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 review proficiency testing (PT) results and take corrective actions for unsuccessful results for one of three Microbiology PT events completed in 2021. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. Review of PT results was required as established in the laboratory's Proficiency Testing procedure located in the Laboratory General Procedures manual. 4. The results from the API 2021 Microbiology 3rd PT event were not found in laboratory records. 5. An API report obtained prior to survey indicated the laboratory received an overall Bacteriology testing score of 97% for the 2021 Microbiology 3rd event. 6. Investigation and corrective action documentation for the unsuccessful scores was not found in laboratory records. The laboratory was unable to provide evidence of PT result review and investigation and corrective action records for this event upon request. 7. In an interview at 12:15 p.m. on 01/11/23, the GS confirmed the above finding. .</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>

This STANDARD is not met as evidenced by:  
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of a non-graded proficiency testing (PT) result for a regulated analyte when the PT program did not evaluate or score the result in two of three 2022 Immunohematology events. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 09/29/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. All non-graded PT results required review and evaluation as established in the laboratory's Proficiency Testing procedure found in the Laboratory General Procedures manual. 4. One compatibility result from the first 2022 Immunohematology/Immunology PT event and one compatibility result from the second 2022 Immunohematology/Immunology event were not graded by API due to lack of consensus. See below. Sample ID Event SER-05 2022 - 1st event SER-06 2022 - 2nd event The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summaries for the above samples were not present in laboratory records. 5. An evaluation of the non-graded results was not found in laboratory records. The laboratory was unable to provide evaluations of the non-graded results upon request. 6. In an interview at 12:15 p.m. on 01/11/23, the GS confirmed the above finding. .

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
 CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:  
 . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2021 and one 2022 non-graded proficiency testing (PT) results for a non-regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Vaginal Wet Preparation (VWP) testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. All non-graded PT results required review and evaluation as established in the laboratory's Proficiency Testing procedure found in the Laboratory General Procedures manual. 4. One VWP result from the third 2021 Hematology/Coagulation PT event and one VWP result from the second 2022 Hematology/Coagulation PT event were not graded by API due to lack of consensus. See below. Sample ID Event VKP-03 2021 - 3rd event VKP-02 2022 - 2nd event The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summaries for the above samples were not present in laboratory records. 5. An evaluation of the non-graded results was not found in laboratory records. The laboratory was unable to provide evaluations of the non-graded results upon request. 6. In an interview at 12:15 p.m. on 01/11/23, the GS confirmed the above finding. .

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate Chemistry reference ranges in the procedure manual for four of six reported Blood Gas parameters and failed to include an accurate female reference range for Erythrocyte Sedimentation Rate. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. A Chemistry 1. Two Abbott i-STAT devices were observed as present and available for use during the tour of the laboratory. 2. Reference ranges for four of six reported parameters were inaccurate or absent in the I-STAT Point of Care Testing Procedure, found in the I-STAT QC and Calibration manual, when compared to a patient Arterial Blood Gas test report from 03/10/22. The inaccurate parameter was Partial Pressure of Oxygen (pO<sub>2</sub>). The absent parameters were Bicarbonate (HCO<sub>3</sub>), Base Excess (BE), and Oxygen Saturation (sO<sub>2</sub>). See below. Patient report from 03/10/22 Parameter Procedure Report pO<sub>2</sub> 80-100 75-100 HCO<sub>3</sub> absent 21-27 BE absent -2 to 3 sO<sub>2</sub> absent 95-99 3. In an interview at 2:45 p.m. on 01/11/23, the GS confirmed the above finding. B. Hematology 1. An Excyte Mini Erythrocyte Sedimentation Rate device was observed as present and available for use during the tour of the laboratory. 2. The reference range for a female patient was inaccurate in the Erythrocyte Sedimentation Rate (ESR) procedure, found in an untitled manual, when compared to a patient ESR test report from 10/08/21. See below. Patient report from 10/08/21 Parameter Procedure Report ESR 0-20 0-30 3. In an interview at 2:50 p.m. on 01/11/23, the GS confirmed the above finding.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete a performance verification (PV) for one non-waived test performed in the laboratory in 2021 and 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. Two Abbot i-STAT devices were observed as present and available for use during the tour of the laboratory. The CHEM8+ cartridge performed on this analyzer was used as a secondary method for the Basic Metabolic Panel of eight analytes. 3. PV documentation for the CHEM8+ cartridge on the i-STAT was not found during review of laboratory records. The laboratory was unable to provide a PV upon request. 4. A PV procedure was not found during review of laboratory procedure manuals. 5. In an interview at 2:40 p.m. on 01/11/23, the GS confirmed the above finding. .

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to establish a function check protocol and perform and document maintenance and function checks for all ancillary laboratory equipment in 2021 and 2022. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. Two Olympus BX43 microscopes and a biosafety cabinet were observed as present and available for use during the tour. 3. The Miscellaneous Instruments and Equipment procedure provided by the laboratory did not include maintenance requirements or function check performance criteria for microscopes or the biosafety cabinet. 4. Documentation of microscope and biosafety cabinet maintenance and function checks was not found in 2021 and 2022 laboratory records. 5. The laboratory was unable to provide this documentation upon request. 6. In an interview at 5:15 p.m. on 01/11/23, the GS confirmed the above finding. 7. The laboratory was given five days to provide documentation of alarm checks completed in 2021 and 2022. In an email received on at 1:18 p.m. on 01/17/23, the GS indicated documentation of microscope and biosafety cabinet 2021 and 2022 maintenance and function checks was not found. .

**D5555**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document alarm system function checks for the blood storage refrigerator with the frequency defined by the laboratory in 2021 and 2022 . Findings are as follows: 1. The laboratory performed Immunochemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on at 8:10 a.m. on 01/11/23. 2. A designated Helmer refrigerator with a temperature alarm system was used to store blood products in the laboratory. 3. Quarterly blood product storage alarm check requirements were established in the Alarm Systems, Temperature procedure located in the Transfusion Services Operations Manual. 4. Blood product storage alarm check records for 2021 and 2022 were not found during review of laboratory records. 5. The laboratory provided approximately 371 Immunochemistry results annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 4:50 p.m. on 01/11/23, the GS confirmed the above finding. 7. The laboratory was given five days to provide documentation of blood product storage alarm checks completed in 2021 and 2022. In an email received on at 1:18 p.m. on 01/17/23, the GS indicated documentation of 2021 and 2022 quarterly alarm checks was not found. .

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(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.

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 two identical Chemistry devices at least twice annually 2021 and 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. Two Abbott i-STAT devices were observed as present and available for use during the tour. The laboratory used the CG4+ (Blood Gas), BNP, and CHEM8+ (Basic Metabolic Panel) non-waived cartridges for testing on these devices. 3. Comparison of duplicate methods was required twice annually as established in the Quality Program Laboratory procedure provided by the laboratory. 4. Comparison of test results obtained from the two i-STAT devices was not found in laboratory records from 2021 and 2022. The laboratory was unable to provide documentation of CG4+, BNP, and CHEM8+ test comparisons upon request. 5. In an interview at 4:30 p.m. on 01/11/23, the GS confirmed the above finding. .

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to ensure comprehensive initial training for three of five new testing personnel (TP) was performed and documented in 2022. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2022 as indicated by the GS during the tour: Siemens Dimension EXL chemistry analyzer Abbott i-STAT devices Sysmex XN-450 hematology analyzer Sysmex CA-600 coagulation analyzer Excyte Mini ESR device Ortho Immunochemistry test system Microscopes and stains for microscopic examinations Fungal exam (KOH) Vaginal preparation (VWP) Gram Stain (GS) Manual differential Body fluid cell counts Leuko EZ Vue test kit Streptococcus Pneumoniae antigen test kit Giardia/Crypto antigen test kit Serum hCG test kit 3. Initial training was required for new testing personnel as established in the Competency Evaluation procedure found in the Laboratory General Procedures manual. 4. Initial training documentation was not found during review of 2022 personnel records as indicated below. GS - none found. The GS performed testing in chemistry, hematology, and immunochemistry TP3 - KOH, VWP, GS Former TP KW - incomplete documentation for chemistry, immunochemistry, and kit testing training 5. The laboratory was unable to provide the missing training records upon request. 6. In an interview at 12:10 p.m. on 01/11/23, the GS confirmed the above finding. .

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunochemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2022 as indicated by the GS during the tour: Siemens Dimension EXL chemistry analyzer Abbott i-STAT devices Sysmex XN-450 hematology analyzer Sysmex CA-600 coagulation analyzer Excyte Mini ESR device Ortho Immunochemistry test system Microscopes and stains for microscopic examinations Fungal exam (KOH) Vaginal preparation (VWP) Gram Stain (GS) Manual differential Body fluid cell counts Leuko EZ Vue test kit

Streptococcus Pneumoniae antigen test kit Giardia/Crypto antigen test kit Serum hCG test kit 3. Semi-annual competency assessment was required for new testing personnel as established in the Competency Evaluation procedure found in the Laboratory General Procedures manual. 4. The GS indicated he began testing in January 2022 during the tour of the laboratory. The GS performed testing in chemistry, hematology, and immunohematology. Initial training documentation was not found during review of personnel records for the GS. See D6120 5. Semi-annual competency assessment documentation for the GS was not found during review of 2022 personnel records. 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 12:10 p.m. on 01/11/23, the GS confirmed the above finding. .

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess competency at least annually for three of three tenured testing personnel (TP) in 2022. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 01/11/23. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2022 as indicated by the GS during the tour: Siemens Dimension EXL chemistry analyzer Abbott i-STAT devices Sysmex XN-450 hematology analyzer Sysmex CA-600 coagulation analyzer Excyte Mini ESR device Ortho Immunohematology test system Microscopes and stains for microscopic examinations Fungal exam (KOH) Vaginal preparation (VWP) Gram Stain (GS) Manual differential Body fluid cell counts Leuko EZ Vue test kit Streptococcus Pneumoniae antigen test kit Giardia/Crypto antigen test kit Serum hCG test kit 3. Annual competency assessments were required for all testing personnel as established in the Competency Evaluation procedure found in the Laboratory General Procedures manual. 4. Annual competency assessment documentation for the above tests was not found during review of 2022 laboratory records for the following TP: TP1, TP2, TP7. 5. The laboratory was unable to provide the missing records upon request. 6. In an interview at 12:10 p.m. on 01/11/23, the GS confirmed the above finding. .