Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651439	03/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lake View Memorial Hospital	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	. The Lake View Memorial Hospital laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on March 13,2023. The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1251 Procedure manual 493.1256 Control procedures 493.1445 Laboratory director responsibilities 493.1451 Technical supervisor responsibilities .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain analytic testing records records from 2023 for at least 2 years. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 03/13/25. 2. Two Siemens Dimension EXL 200 chemistry analyzers and an Abbott i-STAT device were observed as present and available for use during the tour. 3. Comparison of duplicate methods was required twice annually as established in the Quality Program Laboratory procedure. 4. Comparison documentation of test results between these duplicate methods from 2023 was not found during review of laboratory records. The laboratory was unable to provide documentation of test comparisons from 2023 upon request due to an electronic data issue. 5. In an

	interview at 6:05 p.m. on 03/13/25, the GS confirmed the above finding. 6. The laboratory was given an opportunity to obtain the missing data within five days of the survey. The laboratory did not provide the data by 03/18/25. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 Hematology and Chemistry reference intervals in the procedure manual in 2023 and 2024 for three of five hematology analytes reviewed and one of two chemistry analytes reviewed. Findings are as follows: 1. The laboratory performed Hematology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 03/13 /25. 2. A Sysmex XN-450 hematology analyzer and a Siemens Dimension EXL 200 chemistry analyzer were observed as present and available for use during the tour of the laboratory. The laboratory performed Complete Blood Count testing (CBC) on the XN-450 and Glucose testing on the EXL 200. 3. Reference intervals for three of five reviewed CBC analytes were discrepant with the Sysmex XN-450 procedure located in the electronic procedure manual when compared to a patient test report from 11/18 /23 reviewed on date of survey. See below. Analyte Report Procedure RBC 4.63-6.08 4.4-5.9 HGB 13.7-17.5 13.3-17.7 HCT 40.1-51.0 40.0-52.0 4. The Glucose reference interval was discrepant between that established in the GLUC FLEX procedure located in the electronic procedure manual and the value indicated on an patient test report reviewed on date of survey. See below. Analyte Report Procedure Glucose 70-100 60-99 5. In an interview at 3:55 p.m. and 4:40 p.m. respectively on 03/13/25, the GS confirmed the above findings. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the

	laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in an Individualized Quality Control Plan (IQCP) in 9 of 26 months reviewed from 2023 through 2025. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a. m. on 03/13/25. 2. An Abbott i-STAT blood analysis system was observed as present and available for use during the tour. The laboratory performed blood gas analysis using the CG4 cartridge on this device. 3. Two levels of external control material was required every 30 days as established in the IQCP procedure found in the laboratory's IQCP for the i-STAT CG4 cartridge and in the iSTAT Point of Care Testing Procedure located in the electronic procedure manual. 4. The laboratory exceeded the 30 day QC performance time interval nine times in the time frame reviewed, 01/11/23 through 03/13/25, as indicated in the iSTAT QC log. QC was performed as follows: QC date QC date Interval 02/01/23 03/29/23 56 days 09/26/23 10/31/23 35 12/27/23 02/01/24 36 02/26/24 04/25/24 59 04/25/24 06/03/24 39 07/26/24 08/28/24 33 08/28 /24 09/30/24 33 10/30/24 12/12/24 43 12/30/24 02/06/25 38 5. In an interview at 6:05 p.m on 03/13/25, the GS confirmed the above finding. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure testing personnel received comprehensive competency evaluations as required in 2023 and 2024. Findings are as follows: 1. The laboratory was cited for incomplete or absent semi-annual and annual competency evaluations during the previous survey conducted on 01/11/23. 2. During the current survey conducted on 03/13/25, a semi-annual competency assessment from 2023 was not found for one testing personnel. See D6127 3. During the current survey conducted on 03/13/25, annual competency evaluations from 2023 and 2024 were not found for two of seven testing personnel and were incomplete for five of seven testing personnel. See D6128. 4. In an interview at 11:25 a.m. on 03/13/25, the General Supervisor confirmed the above findings. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) (b)(9) 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: . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess competency at least semi-annually for one of one testing personnel hired in 2022. 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 8:08 a.m. on 03/13 /25. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2023 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 BD Bactec blood culture system Microscopes and stains for microscopic examinations Fungal exam Vaginal preparation Urine sediment Gram Stain Manual differential Body fluid cell counts Leuko EZ Vue test kit Streptococcus Pneumoniae antigen test kit Clostridium difficile test kit Giardia /Cryptosporidium 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 electronic procedure manual. 4. Testing personnel 5 (TP5) was hired in June 2022 and completed initial training in August 2022 as indicated in survey notes from the previous survey conducted on 01/11/23. 5. Semi-annual competency assessment documentation for TP5 was not found during review of personnel records. 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 11:25 a.m. on 03/13/25, the GS confirmed the above finding. *This is a repeat finding previously cited during the 01/11/23 survey* .
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 complete comprehensive competency evaluations at least annually for seven of seven testing personnel (TP) in 2023 and 2024. 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 8:08 a.m. on 03/13/25. 2. The following non-waived test systems, analyzers, devices, and test kits were in use in 2023 and 2024 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 (IH) BD Bactec FX40 blood culture system Microscopes and stains for microscopic examinations Fungal exam (KOH) Vaginal preparation (VWP) Urine sediment

	(USed) Gram Stain (GS) Manual differential (Diff) Leuko EZ Vue test kit (Leuk) Streptococcus Pneumoniae antigen test kit (S pneum) Clostridium difficile test kit (C diff) Giardia/Cryptosporidium test kit (G/C) 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. 2023 and 2024 annual competency assessment documentation for the above tests were not found for the GS and TP3 during review of laboratory records. 5. Competency assessments for the following tests were incomplete(I) or not found(0) for the TP indicated below. 2023 EXL TP4-I i-STAT TP4-I XN-450 TP4-I CA-660 TP4-0 ESR TP2-0, TP4-I IH TP2-I, TP4-I FX40 TP4-I, TP6-0 KOH TP4-I VWP TP2-0, TP4-0, TP6-0 USed TP4-0 GS TP4-0, TP6-0 Leuk TP4-I S pneum TP2-0, TP4-0 C diff TP4-I G/C TP4-0 hCG TP4-I 2024 i-STAT TP1-0, TP2-I XN-450 TP1-0, TP2-I FX40 TP1-0, TP2-0, TP4-0, TP5-0, TP6-0 KOH TP1-0, TP2-0 Diff TP1-0, TP2-0 Leuk TP1-0, TP2-0, TP4-0, TP5-0, TP6-0 S pneum TP2-I 6. The laboratory was unable to provide the missing records upon request. 7. In an interview at 12:20 p.m. on 03/13/25, the GS confirmed the above finding. *This is a repeat finding previously cited during the 01/11/23 survey*