Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0663989	06/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mille Lacs Health System	200 North Elm Street, Onamia, 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 Mille Lacs Health System 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 June 13, 2024. The following condition-level deficiency was cited: 493.1250 Analytic Systems, D5400 The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance, D5211 493.1251 Procedure manual, D5401 493.1253 Establishment and verification of performance specifications, D5421 493.1256 Control Procedures, D5445 and D5473 493.1407 Laboratory Director responsibilities, D6013 and D6030 493.1413 Technical Consultant responsibilities, D6046 .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate one unacceptable Chemistry proficiency testing (PT) result out of fifteen challenges completed in 2022 and one unacceptable Hematology PT result out of fifteen challenges completed in 2023. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 06/13/24. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The laboratory received one unacceptable PT result of fifteen Calcium testing challenges completed in 2022 as indicated in API reports. See below. 2022 - 3rd Chemistry core event Test: Calcium Sample: CH-13 Laboratory Result: 1.8 API expected result: 8.9-11.0 4. The laboratory received one unacceptable PT result of fifteen Blood Cell Identification testing challenges completed in 2023 as indicated in

	API reports. See below. 2023 - 1st Hematology event Test: Blood Cell Identification Sample: BCI-04 Laboratory Result: Plasma cell API expected result: Lymphocyte, normal 5. Investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing procedure located in the MLHS Shared Drive electronic procedures folder. 6. Investigation documentation for the unsuccessful Calcium and Blood Cell Identification scores was not found in laboratory records. The laboratory was unable to provide evidence of PT result investigation and corrective action records for these unacceptable results upon request. 7. In an interviews at 10:10 a.m. and 10:20 a.m. on 06/13/24, the GS confirmed the above finding. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on review of laboratory policies and procedures, patient testing and quality control logs, direct observation, and interview with laboratory personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings are as follows: 1. The laboratory failed to follow quality control requirements as established in a Microbiology written procedure . See D5401 2. The laboratory failed to ensure Chemistry reportable ranges obtained during performance verification activities were adopted by the laboratory. See D5421 3. The laboratory failed to perform minimum quality control activities required for a Chemistry test system. See D5445 4. The laboratory failed to document Hematology quality control procedures performed to test stain for intended reactivity. See D5473 .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow quality control requirements in 2022, 2023, and 2024 as established in a Microbiology written procedure. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 06/13/24. 2. A Nanosphere Verigene molecular diagnostic system was observed as present and available for use during the tour. The laboratory performed Clostridium difficile testing using this system. 3. Quality Control (QC) using positive and negative control materials was required with new lots and shipments and every 30 days as established in the Nanosphere Verigene Clostridium difficile (C. diff.) Procedure found in the MLHS

	Shared Drive electronic procedures folder. 4. QC testing with two levels of control materials was performed consistently for new lots and shipments during the time period reviewed, September 2022 through June 2024, as indicated in the C diff (PCR) QC Log found in the Verigene manual. The 30 day interval was missed six times during the this time period. See below. QC date QC date Days elapsed 12/16/22 01/31 /23 46 03/16/23 04/21/23 36 05/18/23 06/21/23 34 07/07/23 08/11/23 35 08/11/23 09 /20/23 40 12/06/23 02/06/24 62 5. In an interview at 4:55 p.m. on 06/13/24, 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 ensure 45 of 53 Chemistry reportable ranges obtained during one of two performance verifications (PV) completed in 2023 were adopted by the laboratory. 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 06/13/24. 2. An Ortho Vitros XT 7600 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer to perform testing in August 2023 as indicated in the test menu spreadsheet provided by the laboratory. 3. PV activities were completed in August 2023 as indicated in records found in the System Verification - Vitros Chemistry Systems manual. The Laboratory Director approved the PV on 08/11/23. 4. The upper and/or lower reportable range limits adopted by the laboratory for 45 of 53 analytes did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in documents found in the System Verification - Vitros Chemistry Systems manual . See below. Analyte PV Adopted ALC 5.9-294.2 10-300 ALKP 15.3-1204.8 20-1500 ALTV 12.0-746.6 4-750 ALB 1.19-6.02 1-6 AMON 8.9-502.3 8.7-500 AMYL 40.4-883.3 30-1200 AST 6.2-706.8 3-750 B12 0-955 159-1000 Bc 0.13-19.53 0-27 Bu 0.51-21.59 0-27 Ca 1.67-13.53 1-14 CK 75.7-1457.5 20-1600 CREA 0.38-13.12 0.15-14 CRP 1.04-9.16 0.5-9 dHDL 6.3-130.9 5-110 dLDL 3.431-117.262 30-350 dTIBC 70.1-639 60-650 ECO2 2.6-35.7 5-40 FE 23.2-594.8 10-600 FEN 0-887 1.25-1000 FT3 0-22.1 0.501-22.785 GGT 27.1-1264.1 10-1400 GLU 34.5-591.5 20-625 LDH 93.5-887.8 41.1000 LIPA 20.7-2138.3 10-2000 mALB 6.70-211.4 6-190 MG 0.67-9.95 0.2-10 NBNP2 0-29800 20-30000 PHOS 1.14-12.95 0.5-13 PROT 3.6-269.5 10-300 PSA 0.0-96.3 0.064-100 SALI 1.44-35.41 1-40 BhCG2 0.033-14400 2.39-15000 TBIL 1.12-18.00 0.1-27 TP 1.97-10.29 2-11 TRIG 10-476.1 10-525 TRPES 0.0-73.0 0.012-80 TSH 0.003-90.1 0.015-100 tVITD 19.8-117 12.8-126 UPRO 7.2-215.0 5-200 UREA 4.4-112.1 2-120 URIC 0.61-16.90 0.5-17 VALP 0.05-122.83 10-150 VANC 0.354-49.165 5-50 A1C 5.108-12.816 4-14 5. In an interview on 06/13/24 at 2:10 p.m., the GS confirmed the above finding. *This is a repeat deficiency. This issue was previously cited during the 09/08/22 survey.* .

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities required for a Chemistry test system in 2023 and 2024. 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 06/13/24. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory began using this analyzer for Hemoglobin A1c (HbA1c) testing in November 2023 as indicated in the test menu spreadsheet provided by the laboratory. 3. Quality control (QC) testing with two levels of control materials was required with new lots and shipments and every 30 days as indicated in the manufacturer's Afinion HbA1c Dx REF1116794 Laboratory Procedure found in the Afinion A1C manual. 4. QC testing with two levels of control materials was performed for new lots and shipments on the following dates in 2023 and 2024 as indicated in the HGBA1C - QC Log found in the Serology QC manual 11/14/23 12/06/23 12/18/23 01/12/24 2/05/24 04/22/24 05/14/24 06/05/24 5. An Afinion HbA1c Individual Quality Control Plan to reduce the frequency of QC performance from 2 levels of control material each day of patient testing was not found in laboratory records. The laboratory was unable to provide an IQCP for the Afinion HbA1c testing upon request. 6. In an interview at 4:18 p.m. on 06/13/24, the GS confirmed the above finding. 7. In an email received at 1:47 p.m. on 06/17/24, the GS indicated 1586 patients had received HbA1c testing on the Afinion analyzer from date of implementation through 06/17/24. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document Hematology quality control (QC) procedures performed to evaluate stain for intended reactivity each day of use from September 2022 through June 2024. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 06/13/24. 2.

	Manual differential stains and an Olympus BX41 microscope used to perform manual blood smears were observed as present and available for use during the tour. 3. The Hematology Quality Control procedure,found in the MLHS Shared Drive electronic procedures folder, did not include direction to perform and document Quality Control activities for manual differential blood smears. 4. Hematology testing for patient MRN# xxx801, which included a blood smear performed on 11/09/22, was reviewed on date of survey. Documentation of acceptable stain intended reactivity was not found for the day of patient testing. 5. In an interview at 3:20 p.m on 06/13/24, the GS confirmed the above finding and stated the laboratory did not document the quality of staining when performing a manual differential. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure analyte reportable range values obtained during a Chemistry performance verification (PV) were adopted by the laboratory in 2023. Findings are as follows: 1. The laboratory was cited for failing to adopt analyte PV reportable range values during the previous survey conducted on 09/08/22. 2. Reportable range values obtained for 45 of 53 analytes during the Chemistry PV completed in 2023 were not adopted by laboratory. This issue was found on date of current survey, 06/13/24. See D5421. 3. In an interview on 06/13/24 at 2:10 p.m., the General Supervisor confirmed the above finding. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 eight of eight testing personnel were evaluated for test procedure competency in all areas of testing in 2022 and 2023. Findings are as

	follows: 1. The laboratory was cited for non-performance of competency evaluations during the previous survey conducted on 09/08/22. 2. Competency evaluations for testing on the Abbott i-STAT blood analyzer were not found on date of current survey, 06/13/24, for eight of eight testing personnel in 2022 and 2023 record. See D6046. 3. In an interview on 06/13/24 at 10:05 a.m., the General Supervisor confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure eight of eight testing personnel were evaluated for test procedure competency in all testing areas in 2022 and 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor (GS) during a tour of the laboratory at 8:00 a.m. on 06/13/24 2. An Abbott i-STAT blood analyzer was observed as present ans available for use during the tour. Chem 8+ and Troponin cartridges were used on this analyzer when the laboratory's primary chemistry analyzer was out of service. 3. The Laboratory Employee Training and Competencies procedure, found in the MLHS Shared Drive electronic procedures folder, indicated testing personnel were evaluated for competency in all testing areas during training, after 6 months of work, and annually thereafter. 4. Competency assessments for testing using the i-STAT analyzer were not included in the Testing Personnel Competency forms completed for eight of eight testing personnel in 2022 and 2023. The laboratory was unable to provide the missing evaluations upon request. 5. In an interview at 10:05 a.m. on 06/13/24, the GS confirmed the above finding. *This is a repeat finding. This issue was previously cited during the 09/08/22 survey.*