Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0663989	07/01/2026
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 30, 2026 and July 1, 2026. The following standard-level deficiencies were cited: 493.1251 Procedure manual 493.1253 Establishment and verification of performance specifications 493.1254 Maintenance and function checks 493.1413 Technical consultant responsibilities .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve five of five new Microbiology protocols implemented by the laboratory in 2025 and 2026. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 11:10 a.m. on 06/30/26. 2. A non-waived 16-module Cepheid GeneXpert System was observed as present and available for use during the tour. The laboratory implemented the following tests using this system as indicated below. Test cartridge Implementation date Xpert Xpress Strep A 10/20/25 Xpert Xpress CoV-2/Flu/RSV plus 10/20/25 Xpert Xpress CoV-2 plus 10/20/25 Xpert CT/NG 04/09/26 Xpert Xpress MVP 04/09/26 3. Performance verification (PV) documentation for the above testing on the GeneXpert System included accuracy verification. Laboratory director approval of each PV was not found. The laboratory was unable to provide this documentation upon request.. 4. 2,040 patient test results from the GeneXpert System were released after test implementation through 06/30/26, as indicated by the TS and listed below. Test cartridge Patient results Xpert Xpress

	Strep A 848 Xpert Xpress CoV-2/Flu/RSV plus 1,065 Xpert Xpress CoV-2 plus 17 Xpert CT/NG 47 Xpert Xpress MVP 63 5. In an interview at 11:15 a.m. on 07/01/26, the TS confirmed the above finding. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 all required Performance Verification (PV) activities prior to reporting patient test results for two of two Chemistry analytes implemented in 2026. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 11:10 a.m. on 06/30/26. 2. An Ortho VITROS 7600 chemistry analyzer and an Abbott i-STAT blood analyzer were observed as present and available for use during the tour. 3. The laboratory implemented the following Chemistry tests in 2026 as indicated below Test Implementation date VITROS Beta hCG2 01/14/26 i-STAT high-sensitivity Troponin I (hs-TnI) 01/22/26 4. PV documentation for the above tests found in the Vitros BhCG2 packet and I STAT HS Troponin manual, respectively, included accuracy, precision, reportable range verification, and laboratory director approval. Reference range verification documentation was not found for either test. 5. Reference range verification was required for new non-waived tests as established in the electronic Standard Protocol for the Introduction of New Testing or Instrumentation policy found in the Mille Lacs Health System shared drive. 6. 39 patient test results were released after test implementation through 06/30/26, as indicated by the TS and listed below. Test Patient results VITROS Beta hCG2 38 i-STAT hs-TnI 1 7. In an interview at 11:18 p.m. on 07/01/26, the TS confirmed the above finding. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for 1 of 2 digital timers in 2026. Findings are as follows: 1. The laboratory performed Bacteriology Gram Stain testing as confirmed by Technical Supervisor (TS) during a tour of the laboratory at

	11:10 a.m. on 06/30/26. 2. An SP digital timer with serial number 240273710 was observed in the Microbiology area during the tour. 3. The manufacturer's calibration expiration date for digital timer 240273710 was 04/02/26 as indicated on the calibration sticker found on the back of the timer. The timer was in use for 89 days after calibration expiration. 4. In an interview at 11:20 a.m. on 06/30/26, the TS confirmed the above finding and discarded the digital timer. 5. A procedure describing a function check protocol for digital timers was not found in the laboratory's electronic procedures found in the Mille Lacs Health System shared drive. 6. In an interview at 11:25 a.m. on 07/01/26, the TS confirmed the lack of a digital timer function check protocol and indicated the laboratory replaced digital timers when the manufacturer's calibration expired. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b)(7) 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; This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure training and competency assessment for two of two new Chemistry analytes was performed and documented for ten of ten testing personnel (TP) in 2026. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 11:10 a.m. on 06/30/26. 2. An Ortho VITROS 7600 chemistry analyzer and an Abbott i-STAT blood analyzer were observed as present and available for use during the tour. 3. The laboratory implemented the following Chemistry analytes on existing instrumentation in 2026 as indicated below. Test Implementation date VITROS Beta hCG2 01/14/26 i-STAT high-sensitivity Troponin I (hs-TnI) 01/22/26 4. Training documentation for the above tests was not found in performance verification documents or personnel folders for ten of ten TP performing Beta hCG2 and hs-Tnl testing in 2026. 5. TP training and competency assessment was required when new methods were introduced as established in the electronic CLIA Compliance Laboratory Competency Program Policy found in the Mille Lacs Health System shared drive. 6. 39 patient test results were released after test implementation through 06/30/26 as indicated by the TS and listed below. Test Patient results VITROS Beta hCG2 38 i-STAT hs-TnI 1 7. In an interview at 11:18 p.m. on 07/01/26, the TS confirmed the above finding. .