Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0663989	09/08/2022
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 failed to ensure one of two performance verifications completed in 2021 was approved, signed, and dated by the laboratory director prior to implementation. 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 09/08/22. 2. A Werfen GEM Premier 5000 blood gas testing system was observed as present and available for use during the tour of the laboratory. The laboratory performed the following tests on this analyzer: pH - Potential of Hydrogen pCO2 - Partial pressure of Carbon Dioxide Na - Sodium K - Potassium Ca - Calcium Cl - Chloride Glu - Glucose Lac - Lactate tHb - Total Hemoglobin pO2 - Partial pressure of Oxygen 3. A performance verification (PV) for the GEM 5000 analyzer, found in the GEM 5000 manual, was completed in June 2021 as indicated in laboratory records. 4. The laboratory director's approval signature and date were not found in the PV documents. 5. In an interview at 1:15 p.m. on 09/08/22, 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 ten of ten reportable ranges obtained during one of two performance verification (PV) activities completed in 2021 were adopted by the laboratory. 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 09/08/22. 2. A Werfen GEM Premier 5000 blood gas testing system was observed as present and available for use during the tour of the laboratory. The laboratory performed the following tests on this analyzer: pH - Potential of Hydrogen pCO2 - Partial pressure of Carbon Dioxide Na - Sodium K - Potassium Ca - Calcium Cl - Chloride Glu - Glucose Lac - Lactate tHb - Total Hemoglobin pO2 - Partial pressure of Oxygen 3. PV activities on the GEM 5000 were completed in June 2021 as indicated in laboratory records found in the GEM 5000 manual. 4. The upper and/or lower reportable range limits adopted by the laboratory did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV EP Evaluator documents and the GEM 5000 Operating Procedure found in the laboratory's electronic chemistry procedure folder . See below. Analyte PV Adopted pH 6.93-7.71 7.0-7.92 pCO2 13-135 6-125 Na 107-171 100-190 K 1.2-10.1 1.0-19.0 Ca 1.0-13.1 0.4-17 Cl 71-155 40-158 Glu 16-672 4-685 Lac 0.4-16.1 0.3-17 tHb 6.8-20.6 3.0-23.0 pO2 31-510 6-690 5. In an interview at 1:30 p.m. on 09/08/22, the GS confirmed the above finding.
D5807	TEST REPORT CFR(s): 493.1291(d) 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. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure four of six reference intervals were consistent between a 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 8:05 a.m. on 09/08/22. 2. A Werfen GEM Premier 5000 blood gas testing system was observed as present and available for use during the tour of the laboratory. The laboratory included the following analytes in the arterial blood gas test performed on this analyzer: pCO2 - Partial pressure of Carbon Dioxide pO2 - Partial pressure of Oxygen HCO3 - Bicarbonate BE - Base Excess sO2 - Oxygen Saturation pH - Potential of Hydrogen 3. Reference intervals listed in the GEM 5000 Operating Procedure, located in the laboratory's electronic chemistry procedures folder, were not consistent with those included on a patient test report from 07/30/21 reviewed on date of survey as indicated below. Analyte Report Procedure pCO2 35-45 32-35 pO2 80-100 83-108 HCO3 22-26 21-28 sO2 - Oxygen Saturation 85-100 94-98 4. In an interview at 3:20 p.m. on 09/08/22, the GS 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 nine of nine testing personnel were evaluated for test procedure competency in all testing areas in 2021. Findings are as follows: 1. The laboratory performed the following microscopic examinations as confirmed by General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 09/08/22: Post Vasectomy Preparation (PV) KOH Preparation (KOH) Vaginal Wet Preparation (VWP) 2. The laboratory's Competency Assessment procedure, found in the electronic procedure folder, indicated testing personnel were evaluated for competency in all testing areas during training, after 6 months of work, and annually thereafter. 3. Competency assessments for PV, KOH, and VWP testing were not included in the Testing Personnel Competency Assessment forms completed for nine of nine testing personnel in 2021. 4. The laboratory was unable to provide the missing evaluations upon request. 5. In an interview at 9:55 a.m. on 09/08/22, the GS confirmed the above finding.