Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0651637	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Mille Lacs Health System - Isle Clinic	**Street Address, City, State** 375 West Isle Street, Isle, 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
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 evaluate an unacceptable proficiency testing (PT) result. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 08/08/18 at 1:00 p.m. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. The laboratory received an unacceptable PT result from API in the first event of 2018 for the analyte and sample listed below. Blood Cell Identification Sample ID Lab Result API expected BCI-03 Neut., hyposeg.* Neut., seg.* 4. An evaluation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide an evaluation upon request. 5. In an interview on 08 /08/18 at 2:10 p.m., TP1 confirmed a documented evaluation of the unacceptable result was not performed. * Note Neutrophil, hyposegmented Neutrophil, segmented
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 Hematology proficiency testing scores when the proficiency testing (PT) program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 08/08/18 at 1:00 p.m. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. A PT result from the first event in 2018 was not graded due to lack of consensus. See below. Sample ID Analyte BCI-01 Blood Cell Identification 4. The API expected results data summary was not present in laboratory records. An evaluation for accuracy of the non-graded result was not found during review of laboratory documents. The laboratory was unable to provide an evaluation of non-graded results upon request. 5. In an interview on 08/08/18 at 2:10 p.m., TP1 confirmed the result had not been evaluated for accuracy.
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 reference intervals were consistent between the hematology reference range chart and patient test reports. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 08/08/18 at 1:00 p.m. 2. A Sysmex KX-21N hematology analyzer was observed as present and available for use during the tour. 3. The reference intervals listed in the Reference Ranges and Critical Values chart, effective date 05/2010, located in the Clinic procedure manual was not consistent with those included on 2 of 2 patient test reports reviewed on date of survey. See below. Patient A - adult male tested on 05/01/17 Analyte* Chart Report WBC 4.6-10.2 4.0-11.0 RBC 4.00-5.80 4.40-5.90 HGB 13.0-17.0 11.7-15.7 HCT 37-50 40.0-53.0 MCV 84-96 78-100 MCH 28-34 27-32 PLT 140-350 150-450 Patient B - adult female tested on 05/01/18 Analyte* Chart Report WBC 4.6-10.2 4.0-11.0 RBC 3.65-5.20 3.80-5.20 HGB 11.0-15.6 11.7-15.7 HCT 33-44.5 35.0-47.0 MCV 81-98 78-100 MCH 27-34 27-32 MCHC 33-35 32-36 PLT 150-410 150-450 4. In an interview on 08/08/18 at 3:00 p.m., TP1 stated the reference ranges listed on the Reference Range and Critical Values chart were in use in the laboratory and confirmed the reference range discrepancy between the chart and the patient test reports. *Note WBC - White Blood Cells RBC - Red Blood Cells HGB - Hemoglobin HCT - Hematocrit MCV - Mean Corpuscular Volume MCH - Mean Corpuscular Hemoglobin MCHC - Mean Corpuscular Hemoglobin Concentration PLT - Platelets