Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0663989	08/09/2018
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
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 Microbiology, Chemistry, Hematology, and Immunohematology 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 Microbiology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/09/18 at 8:25 a.m. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. Ten PT results from 2016, 2017, and 2018 were not graded due to lack of consensus. See below for sample identifications (ID) and analytes. 2016 Sample ID Analyte UDS-05 Benzodiazepine 2017 Sample ID Analyte UA-02 Urobilinogen UR-06 Susceptibility Testing UA-03 Urobilinogen DAT-04 Direct Antiglobulin Test BCH-04 Body Fluid Amylase 2018 Sample ID Analyte CYS-02 Body Fluid Crystals BCI-01 Blood Cell Identification DAT-01 Direct Antiglobulin Test UDS-02 Opiates 4. The API expected results data summaries were not present in laboratory records. Evaluations for accuracy of the non-graded results was not found during review of laboratory documents. The laboratory was unable to provide evaluations of non-graded results upon request. 5. In an interview on 08/09/18 at 1:25 p.m., the GS confirmed the non-graded results had not been evaluated for accuracy.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a blood collection vacutainer used for Hematology tests was not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory performed Hematology (Coagulation) testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/09/18 at 8:25 a.m. 2. BD Sodium Citrate Vacutainer Venous Blood Collection Tubes with lot number 7256765 and expiration date 06/30/2018 were observed as present in the tube rack located in the blood draw area and available for use during the tour. The intended use of these blood collection tubes was for Coagulation testing per the GS and manufacturer's online instructions. 3. In an interview on 08/09/18 at 8:26 a.m., the GS confirmed expired blood collection tubes had been available for use in the blood draw area tube rack.