

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0663989	(X3) Date Survey Completed 11/13/2020
Name of Provider or Supplier Mille Lacs Health System	Street Address, City, State 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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as established in the a Immunology Individualized Quality Control Plan (IQCP) in 3 of 14 months reviewed . Findings are as follows: 1. The laboratory performed Immunology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a. m. on 11/12/20. 2. AmnioSure fetal Rupture of membranes (fROM) test kits were observed as present and available for use during the tour. 3. fROM QC performance was required monthly or on the day of patient testing, whichever is greater, as established in the laboratory's IQCP for the test. 4. Documentation on the QC Log for the fROM test indicated the time interval between fROM QC performance exceeded that established in the IQCP on 1 occasion in the timeframe reviewed, potentially affecting 1 patient test result. See below. QC date: 1/14/2019 Reagent Lot #: 557012573 Expiration Date: 2/4/2020 Patient: Female, aged 35 years Date tested: 4/2 /2019 QC date: 4/25/2019 Reagent Lot #: 560012275 Expiration Date: 7/21/2021 QC interval: 3 months, 1.5 weeks 5. In an interview at 9:30 a.m. on 11/13/20, the GS confirmed the above finding. .</p>

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from the Hematology analyzer and a manual testing method at least twice annually. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 11/12/20. 2. A Sysmex XN-1000 hematology analyzer was observed as present and available for use during the tour. The GS indicated the laboratory performed and reported automated and manual White Blood Cell differential testing. 3. The Sysmex XN-1000 procedure located in the Hematology folder of the on-line Laboratory Manual did not include a requirement to compare automated and manual differential testing twice annually. Twice annual comparisons of these test methods was not found in laboratory records. The laboratory was unable to provide comparison records upon request. 4. In an interview on 11/12/20 at 1:15 p.m., the GS confirmed the above findings. .