

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0651439	(X3) Date Survey Completed 11/08/2018
Name of Provider or Supplier Lake View Memorial Hospital	Street Address, City, State 325 11th Ave, Two Harbors, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain function check records for an Immunohematology centrifuge for at least 2 years. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/08/18 at 8:10 a.m. 2. An Ortho MTS ID-Micro Typing System was observed as present and available for use during the tour. 3. The October 2017 "MTS Centrifuge Check Log (day of use)" document was not present in laboratory records on date of survey. The laboratory was unable to provide the missing document upon request. 4. In an interview on 11/08/18 at 4:10 p.m., the GS indicated the missing function check record could not be located.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>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 Chemistry and</p>

Hematology procedures and patient test reports. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/08/18 at 8:10 a.m. A. Chemistry 1. An i-STAT System analyzer was observed as present and available for use during the tour. 2. The reference intervals listed in the manufacturer's Procedure Manual for the i-STAT System were not consistent with those included on the patient test report reviewed on date of survey as indicated below. Patient - adult female tested on 04/28/18 Analyte* Procedure Report pO2 80-105 80-100 HCO3 22-26 23-27 BE (-)2-(+)3 (-)2-(+)2 O2s 95-98 94-97 3. In an interview on 11/08/18 at 3:30 p.m., the GS confirmed the reference range discrepancy between the procedure and the patient test report. B. Hematology 1. A Sysmex XS-1000i hematology analyzer was observed as present and available for use during the tour. 2. The Mean Platelet Volume (MPV) reference interval listed in the Sysmex XS-1000i Automated Blood Count procedure located in the electronic procedure manual was not consistent with that included on the patient test report reviewed on date of survey. See below. Patient - adult male tested on 07/11/17 Analyte Procedure Report MPV 6.0-11.0 9.1-12.4 3. In an interview on 11/08/18 at 1:55 p.m., Technical Consultant 1 confirmed the reference range discrepancy between the procedure and the patient test report. *Note pO2 - Partial Pressure of Oxygen HCO3 - Bicarbonate BE - Base Excess O2s - Oxygen Saturation

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for 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; (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 supervisor failed to ensure 2 of 3 new testing personnel received documented initial training in 2018. 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 11/08/18 at 8:10 a.m. 2. Review of personnel records indicated documentation of initial training in 2018 for Testing Personnel 5 (TP5) was incomplete for the following: Hematology Coagulation, Erythrocyte Sedimentation Rate Body Fluid Microbiology 3. No training documents were found for Testing Personnel 6 (TP6). 4. The laboratory was unable to provide the missing training documents upon request. 5. In an interview on 11/08/18 at 10:15 a. m., the GS stated all testing personnel were working independently in the laboratory and confirmed the above finding for TP6. In an interview at 11:35 a.m., the Nurse Manager confirmed the above finding for TP5.