Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406304	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lake Region Healthcare - Elbow Lake	1411 Hwy 79 E, Elbow Lake, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to attest to the integration of proficiency testing samples into the routine patient workload on seven occasion in 2019 and twelve occasions in 2020 . 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 05/13/21, at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The Laboratory Director or Designee failed to attest to the integration of PT samples into the routine patient workload for 19 of 31 API PT events reviewed in the January 2019 through May 2021 timeframe. See below. Event Specialty missing attestation 2019-2 Microbiology 2019-2 Chemistry (miscellaneous) 2019-2 Hematology/Coagulation 2019-3 Hematology/Coagulation 2019-1 Immunohematology 2019-2 Immunohematology 2019-3 Immunohematology 2020-1 Microbiology 2020-3 Microbiology 2020-1 Chemistry (core) 2020-2 Chemistry (core) 2020-3 Chemistry (core) 2020-1 Chemistry (miscellaneous) 2020-2 Chemistry (miscellaneous) 2020-1 Hematology 2020-2 Hematology 2020-1 Immunohematology 2020-2 Immunohematology 2020-3 Immunohematology 5. In an interview at 11:25 a.m. on 05/13/21, the GS confirmed the above finding. .
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)

	The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. 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 two non-graded proficiency testing (PT) results for regulated analytes when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 05/13/21. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One activated partial thromboplastin time (aPTT) result from the first 2019 Hematology/Coagulation PT event and one Antibody Screen (AbS) result from the third 2020 Immunohematology event were not graded by API. See below. Event Sample ID Analyte 2019-1 COA-01 aPTT 2020-3 SER-11 AbS 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summaries for the above analytes were not present in laboratory records. Evaluation of the non-graded results was not found in laboratory records. 5. The laboratory's Proficiency Testing procedure did not include direction to evaluate non-graded PT results. The laboratory was unable to provide an evaluation of the non-graded results upon request. 6. In an interview at 11:30 a.m. on 05/13/21, the GS confirmed the above finding. .
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 five non-graded proficiency testing (PT) results for non-regulated analytes when the PT program did not obtain the agreement required for scoring. 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 8:10 a.m. on 05/13/21. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The following analytes were not graded by API due to lack of consensus: One Opiate (Op) result from the first 2019 Chemistry PT event, One Urine Sediment (USed) result and one Vaginal Wet Preparation (VWP) result from the first 2019 Hematology PT event, and One Blood Cell Identification (BCID) result and one USed result from the third 2020 Hematology PT event. Event Sample ID Analyte 2019-1 UDS-01 Op 2019-1 US-02 USed 2019-1 VKP-01 VWP 2020-3 US-06 USed 2020-3 BCI-11 BCID 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summaries for the above analytes were not present in laboratory records. Evaluation of the non-graded results was not found in laboratory records. 5. The laboratory's Proficiency Testing procedure did not include direction to evaluate non-graded PT results. The laboratory was unable to provide an

	evaluation of the non-graded results upon request. 6. In an interview at 11:30 a.m. on 05/13/21, the GS confirmed the above finding. *This deficiency was cited during the 12/11/18 survey* .
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 the reportable ranges obtained during performance verification activities for two of five hematology analytes and one of one chemistry analytes reviewed on date of survey were adopted by the laboratory. Findings are as follows: The laboratory performed Hematology and Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 05/13/21. A. Hematology 1. A Sysmex XN-L 450 hematology analyzer was observed as present and available for use during the tour of the laboratory. 2. Performance verification (PV) activities for the XN-L 450 were completed and the laboratory began testing patient specimens using this analyzer in October 2019 as indicated by the GS. 3. The adopted upper limit of the reportable ranges for Hemoglobin (HGB) and Hematocrit (HCT) did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Adopted HGB 0-25.0 0.1-26.0 HCT 0-71.9 0.2-74.5 4. In an interview at 2:25 p.m. on 05/13/21, the GS confirmed the above finding and indicated the laboratory adopted the manufacturer's analytical measurement ranges as their reportable ranges for the analytes. B. Chemistry 1. A Beckman Coulter Access 2 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 2. Performance verification (PV) activities for the Access 2 were completed and the laboratory began testing patient specimens using this analyzer in May 2019 as indicated by the GS. 3. The adopted upper limit of the reportable range for Thyroid Stimulating Hormone (TSH) did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte PV Adopted TSH 0-48.688 37.5-500 4. In an interview at 4:10 p.m. on 05/13/21, the GS confirmed the above finding. *This deficiency was cited during the 12/11/18 survey* .
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

	493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on review of laboratory policies and procedures, quality control logs, instrument maintenance documents, direct observation, and interview with laboratory personnel, the Laboratory Director failed to ensure previously cited deficiencies were corrected. Findings are as follows: The following deficiencies were cited during the 12 /11/18 survey and were also out of compliance on 05/13/21. 1. D5215 - the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results for non-regulated analytes 2. D5421 - the laboratory failed to ensure the reportable range obtained during performance verification activities for multiple analytes were adopted by the laboratory