Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406304	12/11/2018
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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure microscopic examination proficiency testing was performed consistent with the number of times the laboratory routinely tested patient samples. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) proficiency testing provider. 3. Microscopic examination PT for Blood Cell Identification (BCID) and Fecal Leukocytes, Sperm presence/absence, Vaginal Wet Preparation and Vaginal Wet Preparation (KOH) from API 2017 and 2018 events were completed by multiple testing personnel as indicated on hand written result documents and attestation forms. See below where x indicates the testing personnel completed the microscopic examination PT for that event. Event Testing Personnel 1 2 3 5 2017-3 BCID x x x 2017-3 All others x x 2018-1 BCID x x 2018-1 All others x x 4. In an interview on 12/11/18 at 10:35 a.m., the GS confirmed the PT had been performed by multiple testing personnel prior to the submission date and patient specimens would not routinely be handled in this manner. *D2010 was cited during the 03/02/17 survey*
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to retain quality control and patient testing records for a Microbiology test for at least 2 years. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. 2. Wampole C. Diff Quik Chek test kits were observed as present and available for use during the tour of the laboratory 3. The January 2018 and February 2018 quality control and patient testing logs were not present in laboratory records on date of survey. The laboratory was unable to provide the missing documents upon request. 4. In an interview on 12/11/18 at 4:30 p.m.,the GS indicated the missing documents could not be located. *Note C. Diff - Clostridium difficile
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 review proficiency testing (PT) results from 5 of 11 PT events performed in 2018. In addition, the laboratory failed to investigate unacceptable PT results for 7 analytes in 2018. Findings are as follows: The laboratory performed Microbiology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. The laboratory performed PT using the American Proficiency Institute (API) PT provider. A. Review of Results 1. Review and evaluation of PT results from API was not performed by the laboratory for the 2018 events listed below. Specialty Event Chemistry (Miscellaneous) 2018-1 Chemistry (Core) 2018-2 Microbiology 2018-1 Microbiology 2018-2 Immunohematology 2018-2 2. In an interview on 12/11/18 at 10: 37 a.m., the General Supervisor confirmed the above finding. B. Evaluation of Unacceptable Results 1. The laboratory received unacceptable PT results from API in 2018 for the analytes listed below. Microbiology Event Sample Test* Lab API result 2018-2 GS-11 GS Coccobacilli Rods/Bacilli Chemistry Event Sample Test Lab API result 2018-2 CH-08 Alb 4.5 3.5-4.4 CH-06 Bil T 2.7 1.7-2.6 CH-09 Chol T 77 57-71 CH-09 LDL 22 2-17 Hematology Event Sample Test Lab API result 2018-1 BCI-09 BCID Plasma Cell Nucleated RBC Immunohematology Event Sample Test Lab API result 2018-2 RF-10 RF 1:64/1:80 1:2/1:20 2. An investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation upon request. 3. In an interview on 12/11/18 at 11:20 a.m., the GS confirmed a documented investigation of the unacceptable results was not performed. * Note GS Gram Stain Morphology Alb Albumin Bil T Total Bilirubin Chol T Total Cholesterol LDL Low-density Lipoprotein BCID Blood Cell Identification RF Rheumatoid Factor
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 and Hematology proficiency testing (PT) scores when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. 2. The laboratory performed PT using the American Proficiency Institute PT provider. 3. Two PT results from 2018 were not graded due to lack of consensus. See below for sample identifications (ID) and analytes. 2018 Sample ID Analyte BCI-10 Blood Cell Identification UR-06 Susceptibility 4. The API expected results data summaries were not present in laboratory records. Evaluations for accuracy of the non-graded results were 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 12/11/18 at 11:20 a.m., the GS confirmed the non-graded PT results had not been evaluated for accuracy.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION 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 failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings are as follows: 1. The laboratory failed to include accurate Chemistry reference ranges in the procedure manual. See D5403 2. The laboratory failed to demonstrate a new chemistry analyzer could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. See D5421 4. The laboratory failed to perform and document required Immunohematology equipment maintenance. See D5429 5. The laboratory failed to ensure functions checks for Immunohematology were performed and/or documented as required. See D5431 6. The laboratory failed to perform quality control at least once each day of patient sample testing for a Microbiology test, failed to perform activities as established in an Individualized Quality Control Plan for Microbiology Identification and Sensitivity testing, and failed to perform quality control upon receipt of Microbiology media and discs. See D5445 7. The laboratory failed to ensure all information for Immunohematology quality control was

	documented as required. See D5481 The cumulative effect of the deficient practices constitutes Condition-level noncompliance. *Condition-level noncompliance in analytical systems was cited during the 03/02/17 survey*
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to include accurate Chemistry reference ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. 2. A Siemens Immulite 1000 Analyzer and an Abbott i-STAT Hand Held Blood Analyzer were observed as present and available for use during the tour of the laboratory. 3. The reference range in the PSA - Prostrate Specific Antigen procedure located in the Laboratory Chemistry IA Manual B did not reflect the reference range on the patient test report reviewed on date of survey. See below. Analyte Procedure Report PSA 0.0-0.08 0.08-4.0 4. The reference ranges in the i-STAT - Blood Gases procedure located in the Laboratory Chemistry General Manual A did not reflect the reference ranges on the patient test report reviewed on date of survey. See below. Analyte Procedure Report pH 7.35-7.45 7.34-7.44 pO2 80-105 75-100 BE -2 - +3 0-2.0 5. In an interview on 12/11/18 at 4:15 p.m., the GS confirmed the above findings. .
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 demonstrate a new chemistry analyzer could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. 2. An Abbott i-STAT chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began chemistry testing using this analyzer in December 2017 as indicated in the performance verification documents and confirmed by laboratory personnel during the tour. 2. Laboratory performance verification (PV) studies completed to verify the reportable range of the analytes below did not reach the upper or lower limits of the reportable range adopted by the laboratory. See below. Analyte* PV Adopted pH 6.5-7.91 6.5-8.2 pCO2 19-87.8 5-130 pO2 47-416 5-800 3. In an interview on 12/11/18 at 1:15 p.m., the GS confirmed the laboratory's PV did not verify the upper or lower limit of the reportable ranges adopted from the manufacturer's literature. *Note pH Acidity pCO2 Partial pressure of Carbon Dioxide pO2 Partial Pressure of Oxygen
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform and document required Immunohematology equipment maintenance. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. 2. Ortho MTS Dispensers MT52 and MT52+ were observed as present and available for use during the tour of the laboratory. 3. Requirements for weekly cleaning of the dispensers were established in the ID-MTS Quality Control Record provided by the manufacturer. 4. Laboratory records indicated the cleaning had been performed once per month in the timeframe reviewed, October 2017 - December 2017. 5. In an interview on 12/11/18 at 5:00 p. m., the GS confirmed the above finding.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure daily checks for Immunohematology were performed and documented

	as required. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a..m. 2. Requirements for daily checks were established on the Blood Bank Checklist for the following; centrifuge speed, MTS diluent appearance, incubator temperature, blood appearance, room temperature, refrigerator temperature, water bottle check. 3. The activities above were not performed and documented on 11 /05/17. One patient specimen received Immunohematology testing on this date. 4. In an interview on 12/11/18 at 5:00 p.m., the GS confirmed the above finding.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. 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) at least once each day of patient sample testing for a Microbiology test, failed to perform activities as established in an Individualized Quality Control Plan (IQCP) for Microbiology Identification and Sensitivity testing, and failed to perform QC upon receipt of Microbiology media and discs. Findings are as follows: The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a.m. A. C. Diff Quik Check 1. Wampole C. Diff Quik Chek test kits were observed as present and available for use during the tour of the laboratory 2. QC performance requirements for new test kits were established in the C. Diff Quik Chek - Wampole Kit Test procedure located in Serology Manual D. 3. The laboratory did not complete an IQCP for C. Diff testing to reduce the frequency of QC performance from each day of patient testing. 4. In an interview on 12/11/18 at 2:40 p.m., the GS confirmed an IQCP was not established to reduce the frequency of required QC for C. Diff testing. B. IQCP not followed 1. A BioMerieux Vitek 2 Microbiology analyzer was observed as present and available for use during the tour of the laboratory. Bacterial Identification and Sensitivity testing was performed on this analyzer. 2. Vitek 2 QC performance was required weekly as established in the laboratory's IQCP for the analyzer. 3. The time interval between Vitek QC performance exceeded that established in the IQCP on 1 occasion in the timeframe reviewed, 10/01/18 - 12/11 /18. See below QC date QC date Interval 10/21/18 11/04/18 14 days 4. In an interview on 12/11/18 at 4:35 p.m., the GS confirmed the Vitek 2 QC had not been performed as required in the IQCP. In an email received on 12/20/18 at 1:28 p.m., the GS indicated 5 patient specimens were tested on the Vitek 2 between 10/28/18 and 11/03/18. C. Media QC 1. Microbiology media and discs were observed as present and available for use during the tour of the laboratory 2. Sterility check performance was required upon receipt of media as established in the Quality Control procedure located in the Microbiology Manual. 3. The laboratory did not complete an IQCP to reduce or eliminate the required appearance and ability to support growth checks. 4. Requirements to perform QC upon receipt of discs were not found in laboratory

	procedures. 5. The laboratory did not complete an IQCP to reduce or eliminate QC performance requirements for the discs. 6. In an interview on 12/11/18 at 4:35 p.m., the GS confirmed an IQCP was not in place to reduce or eliminate required QC for Microbiology media and discs.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure all information for Immunohematology quality control was documented as required. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/11/18 at 8:10 a..m. 2. Materials used for Immunohematology testing were documented on the Reagent Log for Blood Bank document each day of patient specimen testing. 3. Materials used on 11/05/17 were not recorded on the document. One patient specimen received Immunohematology testing on this date. 4. In an interview on 12/11/18 at 5:00 p.m., the GS confirmed the above finding.
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 03 /02/17 survey and were also out of compliance on 12/11/18. 1. D5400 - The laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. 2. D2010 - The laboratory failed to ensure microscopic examination proficiency testing was performed consistent with the number of times the laboratory routinely tested patient samples. 3. D6127 - The Technical Supervisor failed to ensure 1 of 1 testing personnel received a competency evaluation at least semiannually during the first year of patient specimen testing.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 1 of 1 testing personnel received a competency evaluation at least semiannually during the first year of patient specimen testing. Findings are as follows: 1. Testing Personnel 2 (TP2) was listed on the Laboratory Personal Report (CLIA) Form CMS-209 as a full time testing personnel. 2. Initial training records indicated TP2 was deemed competent to perform independent laboratory testing in November 2017. 3. A semiannual competency assessment for TP2 was not found during review of laboratory personnel records. The laboratory was unable to provide a semiannual competency assessment for TP2 upon request. 4. In an interview on 12/11 /18 at 9:15 a.m., TP2 confirmed a semiannual competency evaluation had not been completed. *D6127 was cited during the 03/02/17 survey*
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to evaluate 4 of 4 testing personnel for testing competency in 2017. Findings are as follows: 1. The laboratory performed Microbiology, General Immunology, Chemistry, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory 12/11/18/18 at 8:10 a. m. 2. 2017 competency assessments for 4 of 4 tenured testing personnel were not found during review of laboratory records. The laboratory was unable to provide the documents upon request. 4. In an interview on 12/11/18 at 9:05 a.m., the GS confirmed the above finding and Testing Personnel 4 stated the 2017 competency assessments had not been performed.