Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405105	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
River's Edge Hospital	1900 N Sunrise Dr, St Peter, 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
D0000	. The River's Edge Hospital laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey on December 5, 2024. The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1235 Personnel Competency Assessment Policies 493.1236 Evaluation of proficiency testing performance (a), (b)(2) 493.1251 Procedure Manual 493.1291 Test report 493.1451 Technical supervisor responsibilities (b)(7), (b)(8) .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years in 2022 and 2023. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a. m. on 12/04/2024. 2. The laboratory performed Hematology PT using the American Proficiency Institute (API) provider. 3. The following API PT documentation was not present in laboratory records on dates of survey. The laboratory was unable to provide these documents upon request. 2022 - 3rd Hematology/Coagulation event 2023 - 2nd Hematology/Coagulation 2nd event 4. In an interview at 10:10 a.m. on 12/05/2024, the GS confirmed the above finding. .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the Technical Supervisor (TS), Technical Consultant (TC), and General Supervisor (GS) received a competency assessment in 2023 which included the specific TS, TC, and GS position responsibilities listed in Subpart M. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the GS during a tour of the laboratory at 10:45 a.m. on 12/04/2024. 2. The following analyzers, devices, and test systems were observed as present and available for use during the tour: Microscan Autoscan-4 - organism identification and sensitivity Bactec 0950 - blood culture Cepheid GeneXpert - molecular diagnostics Ortho Diagnostics Vitros 5600 - routine chemistry and immunology Radiometer ABL80 - blood gas analysis Sysmex XN-550 - complete blood count and automated differential ACL Top 300 - coagulation analysis Ortho Diagnostics Gel Test System - Immunohematology test system Microscopes for microscopic examination and manual differential Quidel Quickvue Serum HCG test kit Biorad Tox/See toxicology screening test kit 3. A TS, TC, and GS competency assessment was not found during review of 2023 laboratory personnel records. The laboratory was unable to provide the missing competency assessments upon request. 4. A TS, TC, and GS competency assessment procedure was not found in PolicyStat, the laboratory's policy management software. 5. In an interview at 12:40 p.m. on 12/04/2024, the GS confirmed the above finding. .
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 investigate one unacceptable Chemistry proficiency testing (PT) result out of fifteen challenges completed in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 12/04/24. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The laboratory received one unacceptable PT result of fifteen CO2 testing challenges completed in 2023 as indicated in API reports. See below. 2023 - 2nd Chemistry core event Test: CO2 Sample: CH-09 Laboratory result: 17 API expected result: 24-37 4. Unacceptable result investigation and evaluation was required as established in the laboratory's Evaluating Proficiency Testing Results procedure found in PolicyStat, the laboratory's policy management software. 5. Investigation documentation for the unsuccessful CO2 score was not found in laboratory records. The laboratory was unable to provide evidence of PT result investigation and corrective action records for this unacceptable result upon request. 6. In an interview at 10:10 a.m. on 12/05/2024, 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 two non-graded proficiency testing (PT) results for non-regulated analytes when the PT program did not obtain the agreement required for scoring in 2023. Findings are as follows: 1. The laboratory performed B-type natriuretic peptide (BNP) testing and Vaginal Wet Preparation (VWP) testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on at 10:45 a.m. on 12/04/2024. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One BNP result from the 2023 1st Chemistry PT event and one VWP result from the 2023 3rd Hematology PT event were not graded by API. See below. 2023 - 1st Chemistry event Test: BNP Sample ID: CM-05 2023 - 3rd Hematology event Test: VWP Sample ID: VA-03 The API reports referred the laboratory to the expected result data summaries for evaluation of the non-graded test results. The data summaries were not present in laboratory PT records. 4. Non-graded PT result evaluation was required as established in the laboratory's Evaluating Proficiency Testing Results procedure found in PolicyStat, the laboratory's policy management software. 5. An evaluation of the non-graded results was not found in laboratory records. The laboratory was unable to provide evaluations of the non-graded results upon request. 6. In an interview at 10:10 a.m. on 12/05/2024, the GS confirmed the above finding. .
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 ensure the electronic procedure manual included corrective action activities when quality control results were not acceptable for three of eleven test systems in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 12/04 /2024. 2. The following analyzer and test systems were observed as present and available for use during the tour: Cepheid GeneXpert - Microbiology molecular diagnostics Ortho Diagnostics Gel Test System - Immunohematology test system Quidel Quickvue Serum hCG test kit 3. Corrective action instructions for unacceptable quality control results were not included in the test procedures for the above tests systems found in PolicyStat, the laboratory's policy management software. 4. In an interview at 5:30 p.m. on 12/05/24, the GS confirmed the above finding. .
D5807	TEST REPORT CFR(s): 493.1291(d) 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. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with the laboratory personnel, the laboratory failed to ensure a Coagulation reference interval (normal range) was consistent between the procedure and a patient test report in 2024. The findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 12/04 /2024. 2. An ACL Top 300 coagulation instrument was observed as present and available for use during the tour. The laboratory performed Prothrombin Time (PT) testing using this analyzer. 3. Normal ranges were established with each new lot of reagent as indicated in the ACL Top 300 Analyzer Operation Principles procedure found in PolicyStat, the laboratory's policy and procedure software. The procedure referred the user to the current normal range study for normal range information. 4. Reagent lot N0139170 PT normal range was established as 10.7-14.3 and was put into use on 03/29/24 as indicated in the normal range study documentation. 5. The PT normal range included on a patient test report from 07/02/2024 was not consistent with the normal range established for Lot N0139170 . See below. Patient MRN XXX927 Date of test: 07/02/2024 Test report normal range: 11.0-13.6 6. In an interview at 4:45 p.m. on 12/05/24, the GS confirmed the PT normal range established in the study was correct but the laboratory information system (LIS) had not been updated to reflect this values. .
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 observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to ensure comprehensive competency assessments for six of six testing personnel (TP) were performed and documented in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 12/04/24. 2. The following non-waived test kits were observed as present and available for use during the tour. These kits were in use in 2023 as indicated in laboratory records. Quidel Quickvue Serum hCG test kit BioRad Tox/See toxicology screening test kit 3. A competency assessment including all current laboratory tests was required for testing personnel during initial training, semi-annually the first year of testing, and annually thereafter as established in the Lab Operations Department Competency Procedure found in PolicyStat, the laboratory's policy management software. 4. The BioRad Tox/See toxicology test was not included in the 2023 Initial Hire/6 Month /Annual MLT/MLS Competency Verification form for six of six TP. 5. The Serum hCG test was included in a grouping of tests on the 2023 Initial Hire/6 Month/Annual MLT/MLS Competency Verification form for six of six TP. Documentation in this area of the form was not specific to Serum hCG test competency assessment. 6. In an interview at 2:40 p.m. on 12/04/24, the GS confirmed the BioRad Tox/See test was not included in 2023 competency assessments. The GS also indicated Serum hCG testing competency was assessed during initial training but not specifically included in competency assessments after the initial assessment. .
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to perform direct observation of test performance for all analyzers, devices, and test systems in the laboratory in 2023 for five of five testing personnel (TP) during semi-annual and/or annual competency assessments. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 12/04/2024. 2. The following analyzers, devices, and test systems were observed as present and available for use during the tour: Microscan Autoscan-4 - organism identification and sensitivity Bactec 0950 - blood culture Cepheid GeneXpert - molecular diagnostics Ortho Diagnostics Vitros 5600 - routine chemistry and immunology Radiometer ABL80 - blood gas analysis Sysmex XN-550 - complete blood count and automated differential ACL Top 300 - coagulation analysis Ortho Diagnostics Gel Test System - Immunohematology test system Microscopes for microscopic examination and manual differential Quidel Quickvue Serum HCG test kit Biorad Tox/See toxicology screening test kit 3. Competency assessment including direct observation of test performance for all current laboratory tests was required for testing personnel during initial training, semi-annually the first year of testing, and annually thereafter as established in the Lab Operations Department Competency Procedure found in PolicyStat, the laboratory's policy management software. 4. Direct observation of test performance for the above analyzers, devices and test systems was included on the

	Initial Hire/6 month/Annual MLT/MLS Competency Verification form.. The forms indicated direct observation had been completed for five of five TP in 2023. 5. The laboratory performed approximately 134,650 tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 12:25 p. m. on 12/04/2024, the GS indicated direct observation of test performance was not completed for semi-annual or annual competency assessments unless a process or policy had been changed. .
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the technical supervisor failed to evaluate direct observation of instrument maintenance for all analyzers, devices, and test systems in the laboratory in 2023 for five of five testing personnel (TP). Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 12/04/2024. 2. The following analyzers, devices, and test systems were observed as present and available for use during the tour: Microscan Autoscan-4 - organism identification and sensitivity Bactec 0950 - blood culture Cepheid GeneXpert - molecular diagnostics Ortho Diagnostics Vitros 5600 - routine chemistry and immunology Radiometer ABL80 - blood gas analysis Sysmex XN-550 - complete blood count and automated differential ACL Top 300 - coagulation analysis Ortho Diagnostics Gel Test System - Immunohematology test system 3. Competency assessment including direct observation of instrument maintenance for all current laboratory tests was required for testing personnel during initial training, semi-annually the first year of testing, and annually thereafter as established in the Lab Operations Department Competency Procedure found in PolicyStat, the laboratory's policy management software. 4. The Initial Hire/6 month /Annual MLT/MLS Competency Verification form included direct observation of instrument maintenance for the above analyzers, devices and test systems. The forms indicated direct observation of instrument maintenance had been completed for five of five TP in 2023. 5. The laboratory performed approximately 134,650 tests annually as indicated on the Form CMS-116 provided by the laboratory on the date of survey. 6. In an interview at 12:25 p.m. on 12/04/2024, the GS indicated direct observation of instrument maintenance was not performed for semi-annual or annual competencies unless a process or policy had been changed. .
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 observation, document review and interview with laboratory personnel, the Technical Supervisor (TS) failed to complete a competency assessment at least semi-annually during the first year of patient specimen testing for two of five testing personnel (TP) in 2023. The findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a. m. on 12/04/2024. 2. The following non-waived test systems, analyzers, devices, and test kits were in use as indicated by the GS during the tour. Ortho Vitros 5600 chemistry and immunology analyzer Radiometer ABL80 blood gas analyzer Sysmex XN-550 hematology analyzer ACL Top 300 coagulation analyzer Cepheid GeneXpert molecular diagnostics instrument Microscan Autoscan-4 organism identification and sensitivity analyzer BacTec 0950 blood culture instrument Ortho Diagnostics Gel test system for Immunohematology testing Microscopes for microscopic examinations and manual differentials BioRad Tox/See urine toxicology screen test system Quidel Quickvue Serum HCG kit test 3. Semi-annual competency assessments were required for new testing personnel in their the first year of patient specimen testing as established in the Lab Operations Department Competency Procedure found in PolicyStat, the laboratory's policy management software. 4. Initial training was performed and documented for the TS in May 2023 and for TP3 in March of 2023 as indicated on the Initial Hire/6 Month/Annual MLT/MLS Competency Verification forms. 5. Semi-annual competency assessment documentation for the TS and TP3 was not found in 2023 personnel records. The laboratory was unable to provide these semi-annual competency documents upon request. 6. In an interview at 2:40 p.m. on 12/04 /2024, the GS confirmed the above finding. .