Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405105	11/28/2018
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
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 calibration records for a Chemistry analyzer. Findings are as follows: A. Calcium 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/27/18 at 10:05 a. m. 2. An Abbott Architect ci4100 Chemistry analyzer was observed as present and available for use during the tour. 3. The Architect Serum / Urine Calcium Instruction for Use, and the Chemistry Department Calcium procedure, indicated that calibration of the Calcium assay is required by the manufacturer to be performed every 30 days. 4. Review of the Calcium Cal Curve Summary Report revealed that documentation of calibrations performed between 9/14/2017 (with reagent lot = 82307UN16) and 5/7 /2018 (with reagent lot = 80658UN17) were missing. The laboratory was unable to provide the missing records upon request. 5. In an interview on 11/28/2018 at 11:00 a. m., GS1 indicated that the calibrations had been performed, but that the instrument database had not properly retained entries of such. B. Total PSA 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/27/18 at 10:05 a.m. 2. An Abbott Architect ci4100 Chemistry analyzer was observed as present and available for use during the tour. 3. The Architect Total PSA Instruction for Use, and the Chemistry Department Total PSA procedure, did not provide a requirement for the frequency of PSA calibrations. 4. Review of the Total PSA Cal Curve Summary Report revealed that documentation of calibrations performed between 6/27/2017 (with reagent lot = 7003FN00) and 7/5 /2018 (with reagent lot = 82044FN00) were missing. The laboratory was unable to

	provide the missing records upon request. 5. In an interview on 11/28/2018 at 11:00 a. m., GS1 indicated that the calibrations had been performed, but that the instrument database had not properly retained entries of such. .
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 non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/27/18 at 10:05 a.m. 2. The laboratory performed PT using the American Association of Bioanalysts (AAB) as PT provider. 3. The laboratory received non-graded results from AAB due to no consensus for the events and tests listed below. Event = 2017 - Chemistry - Quarter 2 Sample ID = Specimen #5 Test = Troponin Event = 2017 - Chemistry - Quarter 3 Sample ID = Specimens #1 & #2 Test = Urine Amylase Event = 2018 - Chemistry - Quarter 2 Sample ID = Specimen #1 Test = Urine Total Protein Event = 2018 - Non Chemistry - Quarter 1 Sample ID = Specimens #4 & #5 Test = Anti Hepatitis B Surface Antigen 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 11/27/18 at 12:30 p.m., GS1 confirmed the above findings. .
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 non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor 1 (GS1) during a tour of the laboratory on 11/27/18 at 10:05 a.m. 2. The laboratory performed PT using the American Association of Bioanalysts (AAB) as PT provider. 3. The laboratory received non-graded results from AAB due to no consensus for the event and test listed below. Event = 2017 - Non Chemistry - Quarter 1 Sample ID = Specimens #2 & #5 Test = Rheumatoid Factor 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 11/27/18 at 12:30 p.m., GS1 confirmed the above findings.