Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405105	11/18/2022
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
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 verify 57 of 57 reference intervals (normal ranges) were appropriate for the laboratory's patient population during two of two new analyzer performance verification (PV) activities completed in 2021. Findings are as follows: 1. The laboratory performed Chemistry and Virology testing as confirmed by General Supervisor 2 (GS2) during a tour of the laboratory at 9:40 a.m. on 11/17/22. 2. Two Ortho Clinical DiagnosticsVitros 5600 analyzers were observed as present and available for use during the tour of the laboratory. The laboratory began testing on the two Vitros 5600 analyzers on 1/05/22 as confirmed by an email received by GS2 at 2:08 p.m., on 11/18/22. 3. PV activities on the Vitros 5600 analyzers were performed in June 2021 as indicated on laboratory records found in the Vitros 5600 System Verification manuals. The normal range verification documentation for 57 analytes tested on the Vitros 5600 analyzers was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 4. In an interview at 3:05 p.m. on 11/17/22, GS2 confirmed the above finding and stated the normal range verification has been in progress since 1/05/22 and the verification has not been completed. 5. In an email received at 12:09 p.m. on 11/23/22, GS2 indicated approximately 50,600 tests were performed annually on the Vitros analyzers.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure Histopathology test result reports included the name and address of the laboratory location in 2022. Findings are as follows: 1. The laboratory performed frozen sections under the subspecialty of Histopathology as confirmed by General Supervisor 2 (GS2) during a tour of the laboratory at 9:40 a.m., on 11/17/22. 2. The laboratory began performing frozen sections on 10/24/22, as indicated in laboratory records. 3. The name and address of the laboratory location, Rivers Edge Hospital, 1900 N. Sunrise Dr., St. Peter, MN 56082, was not included on the frozen section interoperative consultation test report dated 10/24/22, reviewed on the day of survey 11/17/22. 4. The laboratory performed one frozen section annually as indicated on the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Form CMS-116, provided by the laboratory on the date of survey. 5. In an interview at 4:30 p.m. on 11/17/22, GS2 confirmed the above finding. .