Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1021726	04/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Scenic Rivers Health Services - Eveleth	239 Mckinley Avenue, Eveleth, 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 ensure 2 of 5 reportable ranges obtained during performance verification activities were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 1:00 p.m. on 04/26/22. 2. A Sysmex XN-330 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities on the XN-330 for Red Blood Cells, White Blood Cells, Hemoglobin, Hematocrit, and Platelets were completed in December 2021 as indicated in laboratory records. 4. The upper limit of the reportable range for Hemoglobin (HGB) and Hematocrit (HCT) in the Sysmex XN-330 procedure, found in the Eveleth Laboratory manual, did not reflect the actual reportable range value obtained by the laboratory during the PV. The values listed in the procedure were the manufacturer's stated reportable ranges. See below. Analyte PV Procedure HGB 0-24.8 0.1-26.0 HCT 0-72.3 0.1-74.5 5. In an interview at 3:10 p.m. on 04/26/22, the TC confirmed the above finding. .