Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0455989	07/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lexington Regional Health Center	1201 N Erie Street, Lexington, NE	

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 surveyor review of new instrumentation logs, lack of documentation, and interview with the laboratory supervisor the laboratory failed to verify precision for a new sedimentation rate instrument. 1. Review of new instrumentation revealed the laboratory started patient testing on January 2021 with a new sedimentation rate instrument. The laboratory performed two hundred and twenty seven sedimentation rate tests to date with the new instrument. 2. Review of the validation of performance specifications for the new sedimentation rate instrument revealed no run to run precision studies had been performed. 3. Interview with the laboratory supervisor on 7/15/2021 at 3:37 PM confirmed run to run precision was not performed prior to patient testing.