Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 28D0454750	**(X3) Date Survey Completed** 04/29/2025
Name of Provider or Supplier Community Medical Center	**Street Address, City, State** 3307 Bill Schock Boulevard, Falls City, 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) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 list, list of tests performed, lack of documentation, and interview with the laboratory manager, the laboratory failed to verify precision on the laboratory's new sedimentation rate analyzer, Diesse Mini Cube. 1. Review of new instrumentation list revealed the laboratory started patient testing on August 2024 on the new sedimentation rate analyzer, Diesse Mini Cube. 2. Review of the laboratory's list of tests performed revealed the laboratory tested 299 patients using the new sedimentation rate analyzer. 3. Review of the validation of performance specifications for the new sedimentation rate analyzer revealed no run to run precision studies had been performed. 4. Interview with the laboratory manager on 4/29/2025 at 12:36 PM, confirmed run to run precision was not performed prior to patient testing.