

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0681465	(X3) Date Survey Completed 08/16/2023
Name of Provider or Supplier Kimball Health Services	Street Address, City, State 255 W 4th St, Kimball, 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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>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 technical consultant, the laboratory failed to verify precision on the laboratory's new sedimentation rate analyzer, Mini Cube. 1. Review of new instrumentation list revealed the laboratory started patient testing on December 2022 on the new sedimentation rate analyzer, Mini Cube . 2. Review of the laboratory's list of test performed revealed the laboratory had tested 177 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 technical consultant on 8/16/2023 at 9:43 AM confirmed run to run precision was not performed prior to patient testing.</p>