

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385424	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier Hegg Health Center	Street Address, City, State 1202 21st Avenue, Rock Valley, IA	
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>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Siemens DCA Vantage performance specification records and confirmed by interview with General Supervisor (GS) #1 at 10:15 am on 06/18/2025, the laboratory failed to verify the performance specifications of precision and reportable range prior to testing and reporting patient specimens for the analytes, urine microalbumin and urine creatinine. The findings include: 1. The laboratory installed a new Siemens DCA Vantage instrument and began using it to perform patient urine microalbumin and urine creatinine testing in March 2024. 2. Review of the performance specification verification records for the Siemens DCA Vantage did not include the precision and reportable range for the analytes, urine microalbumin and urine creatinine. 3. At the time of the survey, GS #1 confirmed the laboratory failed to have documentation of performance specification verification records for precision and reportable range for urine microalbumin and urine creatinine testing performed on the Siemens DCA Vantage.</p>