

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382761	(X3) Date Survey Completed 12/03/2021
Name of Provider or Supplier Guthrie County Hospital	Street Address, City, State 710 North 12th Street, Guthrie Center, 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>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 lack of performance specification records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:40 pm on 12/03/2021, the laboratory failed to verify the performance specifications of accuracy and precision for the test system, Qiagen Qia-Stat, prior to testing and reporting patient test results. The findings include: 1. The laboratory began using the Qiagen Qia-Stat test system to perform respiratory panel testing in October 2020. 2. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have performance specification records for the Qiagen Qia-Stat test system.</p>