

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384559	(X3) Date Survey Completed 04/10/2025
Name of Provider or Supplier Floyd County Memorial Hospital	Street Address, City, State 800 11th Street, Charles City, 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 Abbott iStat performance specification records and confirmed by interview with Technical Supervisor (TS) #1 at 1:45 pm on 04/10/2025, the laboratory failed to verify the performance specification of reportable range prior to testing and reporting patient specimens for the analytes: pH, partial pressure of oxygen (PO2), and partial pressure of carbon dioxide (PCO2). The findings include: 1. The laboratory began using two Abbott iStat test systems (Instrument 1 and Instrument 2) to perform pH, PO2, and PCO2 patient testing on the EG6+ test cartridges in November 2024. 2. Review of the performance specification verification records for Instrument 1 and Instrument 2 indicated the laboratory failed to verify the reportable range for pH, PO2, and PCO2 on both instruments. 3. At the time of the survey, TS #1 confirmed the laboratory failed to have documentation of verification of the performance specification of reportable range for pH, PO2, and PCO2 on both instruments.</p>