

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2171040	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Lafayette Regional Health Center-Er Stat Lab	Street Address, City, State 1500 State Street, Lexington, MO	
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 review of the performance verification procedures for the i-Stat blood gas testing and interview with the laboratory manager, the laboratory failed to verify reference intervals(normal values). Findings: 1. Review of the verification procedures for the i-Stat analyzer for pH, pCO2, PO2, Sodium, Potassium, Glucose and Ionized Calcium showed no verification of normal values. 2. Interview with the laboratory manager on September 16, 2020 at 11:30 AM confirmed the laboratory failed to ensure the verification procedures for normal values for the i-Stat analyzer were appropriate for the laboratory's patient population.</p>