

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442499	(X3) Date Survey Completed 06/02/2026
Name of Provider or Supplier Cockerell & McIntosh Pediatrics - Blue Springs	Street Address, City, State 1203 S 7 Hwy, Blue Springs, 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	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (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. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Advanced bilirubin STAT analyzer, patient results and interview with the technical supervisor (TS), the laboratory failed to verify performance specifications for total bilirubin prior to reporting patient test results. Findings: 1. Review of the performance verification procedures for the Advanced bilirubin STAT analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analyte: total bilirubin prior to the beginning of patient testing in September 2025. 2. The laboratory performs approximately 20 total bilirubin patient tests annually. 3. Interview with the TS on June 2, 2026 at 2:30 PM confirmed the laboratory failed to verify performance specifications for total bilirubin prior to reporting patient test results.