

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2142164	(X3) Date Survey Completed 11/07/2019
Name of Provider or Supplier Jeffers, Mann & Artman Pediatrics And	Street Address, City, State 5029 Arco Street, Cary, NC	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of quality control (QC) records and interview with technical consultant (TC) 11/7/19, the laboratory failed to use the laboratory's established QC ranges for the bilirubin testing performed on the Advanced Instruments BR2 STAT Bilirubin analyzer as required by the manufacturer. Findings: Review of manufacturer's instructions for BIO-RAD Liquichek Pediatric quality control reagents revealed "Assignment of Values...It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of the control." Review of QC records for the BR2 STAT bilirubin analyzer revealed the laboratory had established QC ranges for the BIO-RAD Liquichek Pediatric Control Levels 1 and 2, Lot #'s 44311 and 44312, in December of 2018. Review of QC records revealed the laboratory failed to use the laboratory's established values from August 12 to October 30, 2019, a period of approximately 3 months in which the manufacturer's values were used to determine QC acceptability. Approximately 10 patients were tested from August 12 to October 30, 2019. During interview at approximately 1:00 p.m. the TC confirmed the laboratory had not used the laboratory's established values to determine QC acceptability as required from August 12 to October 30, 2019.</p>