

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2210862	(X3) Date Survey Completed 10/31/2023
Name of Provider or Supplier Reproductive Specialists Of The Carolinas	Street Address, City, State 1918 Randolph Road, Suite 410, Charlotte, 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
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 performance verification records for the Cobas e 411 analyzer, review of 2023 calibration verification records, and interview with the laboratory director (LD) 10/31/23, the laboratory failed to verify the maximum reportable range for the prolactin (PROL) testing performed on the Cobas e 411 analyzer. Findings: The laboratory began patient testing on Cobas e 411 analyzer in December of 2022. Review of performance verification records for PROL, EP Evaluator print date August 3, 2022, revealed the laboratory has a reportable range of 0.047 to 470 ng/mL. The highest values obtained for the verification were 305.1 ng/mL, 309.4 ng/mL and 306.7 ng/mL. The values obtained failed to verify the maximum reportable range of 470 ng/mL. Review of calibration verification records for PROL, dated 7/24/23, revealed a mean of 323.53 ng/mL. The value fails to verify the maximum reportable range of 470 ng/mL. Interview with LD at approximately 11:00 a.m. confirmed the reportable range for the PROL testing on the Cobas e 411 analyzer is 470 ng/mL.</p>