

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2279117	<b>(X3) Date Survey Completed</b>  08/06/2024
<b>Name of Provider or Supplier</b>  Reproductive Medicine And Infertility Associates	<b>Street Address, City, State</b>  12000 Elm Creek Blvd, Maple Grove, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure eight of eight analyte reportable ranges obtained during one of one performance verifications (PV) completed in 2024 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed General Immunology and Endocrinology testing as confirmed by the Technical Supervisor (TS) and Technical Consultant 1 (TC1) during a tour of the laboratory at 10:00 a.m. on 08/06 /24. 2. A Roche Cobas e411 analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began testing patient specimens using this analyzer on 01/08/24. 3. PV activities were completed in December 2023 as indicted in records found in the Roche Analyzers Verification Studies manual. The Laboratory Director approved the PV on 12/18/23. 4. A PV procedure was not found in laboratory procedure manuals. The laboratory was unable to provide a PV procedure upon request. 5. The upper and/or lower reportable range limits adopted by the laboratory for eight of eight analytes did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in EP Evaluator Linearity Regression Summaries found in the Roche Analyzers Verification Studies manual . See below. Analyte Obtained Adopted Estradiol 28.883-2925.333 5-3000 hCG 0.3000-174.4667 0.100-10,000 Prolactin 1.300-8879.000 0.0470-470 TSH</p>

0.9557-198.3667 0.005-100 Progesterone 0.3937-53.9900 0.05-60 LH 1.420-447.267  
0.100-200 FSH 0.7577-475.333 0.3-200 Rubella 0.1150-87.3533 0.210-500 6. In an  
interview at 11:10 a.m. on 08/06/24, the TS and TC1 confirmed the above finding and  
indicated the manufacturer's analytical measuring range for the analytes had been  
adopted. .