

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0989448	(X3) Date Survey Completed 06/05/2025
Name of Provider or Supplier Reproductive Medicine Group Llc, The	Street Address, City, State 612 Medical Care Dr, Brandon, FL	
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
D0000	An announced CLIA recertification survey was conducted at The Reproductive Medicine Group LLC on 6/5/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview it was determined the laboratory safety procedures failed to be established and observed to ensure protection from physical hazards for three of three chemicals. Findings included: 1. Wright's Dip Stat #1, #2, and #3 chemicals used for hematology sperm testing were observed on 6/5/25 at 9:50 a.m., stored in a cabinet under the laboratory sink. All three chemicals had the fire image on the labeling as well as a danger notice "highly flammable liquid". Signage on the outside of the cabinet door indicated Hazardous Chemicals were stored there. There was no safety cabinet to store the chemicals in observed. 2. The Technical Consultant confirmed on 6/5/25 at 9:50 a.m., the Wright's Dip Stat #1, #2, and #3 chemicals were not safely stored and should be stored in a safety cabinet. The Technical Consultant confirmed there was not a safety cabinet available at the time of the survey.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty</p>

assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to verify the accuracy of Hematology Sperm Morphology for 3rd event of 2023 and 1st event of 2025 assigned a proficiency testing scores that did not reflect laboratory test performance. Findings included: 1. The American Proficiency Institute (API) proficiency performance evaluations for Hematology Sperm Morphology for 3rd event of 2023 documented for SCL-14, SCL-19, SCL-20, and SM-04 and for 1st event of 2025 for SCL-04, SCL-06, SCL-07, and SCL-08 "Not Graded" and "See Data Summary". The Performance Review and Corrective Action Documentation form for 3rd event of 2023 and 1st event of 2025 did not document any verification of accuracy or review of the Data Summary. 2. The Technical Consultant confirmed on 6/5/25 at 11:10 a.m., there was no documentation of verification of the Hematology Sperm Morphology for 3rd event of 2023 and 1st event of 2025 assigned a proficiency testing scores that did not reflect laboratory test performance.