

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2274130	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 100 Town Square Pl, Jersey City, NJ	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Procedure Manual and interview with the Technical Supervisor (TS), the Laboratory failed to establish a procedure for validating Andrology testing from 12/27/22 to 11/22/24. The TS confirmed on 11/19/2024 at 11:00am that the laboratory failed to have the aforementioned procedure.</p>
D6086	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Performance Specifications (SP) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Andrology tests from 12/27/22 to the 11/19/24. The TS confirmed on 11/19/24 at 11:15 am that SP were not adequate.</p>