Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0999230	12/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates	81 Veronica Avenue, Somerset, 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	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to follow all procedures written for "Laboratory Quality Control and Quality Assurance" from September 2021 to the date of the survey. The findings include: 1. The procedure "Laboratory Quality Control and Quality Assurance" stated "Accubeads: New reagent lot # is to be/will be counted/quantified at least 30 times and results collated and be evaluated to the package insert data/results for comparison. 2. There as no documented evidence the above mentioned procedure was performed on the lot #202411181 and 20171135 being used at the time of survey. 3. The TP confirmed on 12/8//22 at 1:30 pm that the laboratory did not follow the PM.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the

	methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify QC material before use for Semen Analyses from September 2021 to the date of survey. The TP confirmed 12/8 /22 at 1:15 pm that QC material was not verified before putting in use.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR), Work Records (WR) and interview with the Testing Personal (TP), the laboratory failed to have WR on one out of five FR reviewed from 6/22/22 to the date of the survey. The TP confirmed on 12/8 /22 at 1:00 pm that the laboratory did not maintain all work records..