Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0919498	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Reproductive Medicine Associates	**Street Address, City, State** 60 Columbia Road, Morristown, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory reagents, and interview with theOffice Manager (OM), the laboratory failed to ensure protection from chemical and physical hazards from 7/27/21 to the date of survey. The findings include: 1. All flammable and inhalation risk reagents were not kept in a flammable cabinet. 2. Flammable reagents where observed under the laboratory sink. 3. The OM confirmed on 10/17/23 at 11:00 pm that the laboratory did not ensure protection from chemical and physical hazards.
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 Leucoscreen reagents and interview with the Office Manager (OM), the laboratory failed to have a procedure on making Leucoscreen staining reagent from 7/27/21 to the date of survey. The findings include: 1. The Leucoscreen staining regent was kept in a specimen

	collection container wrapped in tinfoil with Leucoscreen and expiration date 10/20/23 written in black marker on it. 2. The GS stated that "The laboratory makes the stain at an offsite location". 3. There was no procedure in the PM on how to prepare the Leucoscreen staining reagent. 4. The OM confirmed on 10/17/23 at 10:45 pm that the laboratory failed to have the above mentioned procedure.
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 surveyor review of Quality Control (QC) records and interview with theOffice Manager (OM), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Semen Anaylisis tests 7/27/21 to the date of survey. The finding includes: 1. There was no documented evidence that Accubead Lot numbers 211712351 and 21210181 were verified before being put into use. 2. The OM confirmed on 10/17/23 at 10:20 am that the QC material was not verified before putting in use.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on the lack of Performance Specifications (PS) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure the PS procedures for Semen Analysis (SA) and Anti Sperm Antibodies (ASA) tests were adequate on the date of survey. The findings include: 1. The laboratory moved to a new address August 2023 2. There was no evidence that PS was performed for SA and ASA after the laboratory changed locations. 3. The OM confirmed on 10/17/23 at 11:30 pm the LD failed to ensure the PS were adequate.