Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2120264	(X3) Date Survey Completed 07/27/2021
Name of Provider or Supplier Reproductive Medicine Associates	**Street Address, City, State** 95 Old Marlton Pike West, Marlton, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of Competency Assessment (CA) records and interview with the Laboratory Manager (LM), the laboratory failed to follow written procedures to perform a CA on six of six Testing Personnel for the calendar years 2019 and 2020. The LM confirmed on 7/27/21 at 11:30 am that the CA procedure was not followed .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to evaluate coded results obtained from the American Association of Bioanalysts (AAB) for Andrology & Embryology events from May 2020 to the date of survey. The findings include: 1. The laboratory did not evaluate Code ? (This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus) response from AAB for the following: a) Antisperm Antibody IgG+IgA in Andrology & Embryology events S1, S2 2020 and S1 2021. b) Sperm Cell ID and Sperm Motility in Andrology & Embryology event S2 2020. c) Sperm Count Traditional in

	Andrology & Embryology event S1 2021. 2. The LM confirrmed on 7/27/21 at 10:00 am that the laboratory failed to evaluate the above mentioned coded results.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty 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 surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to verify the accuracy of Andrology test results obtained from the American Association of Bioanalysts (AAB) from May 2020 to the date of survey. The findings include: 1. The laboratory received a 100 but results were not graded. 2. There was no documented evidence the laboratory verified: a) Antisperm Antibody IgG+IgA in Andrology & Embryology events S1, S2 2020 and S1 2021. b) Sperm Cell ID and Sperm Viability in Andrology & Embryology event S2 2020. c) Sperm Count Traditional in Andrology & Embryology event S1 2021. 2. The LM confirmed on 7/27/21 at 12:15 pm accuracy of the PT results were not verified
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Bio Rad Manufacture Package Insert (MPI) and interview with the Laboratory Manager (LM), the laboratory failed to follow the MPI for control material used on the Centaur CP from 1/23/19 to the date of the survey. The findings include: 1. The LM stated that the laboratory used the MPI control ranges. 2. A review of Quality Control (QC) documentation revealed QC ranges were outside the MPI range as below: BioRad Controls Lot: 40371, 40372 and 40373 expiration date: 10/31/2021 a. Estradiol (E2) - Level 1: MPI 57.2 - 96.6 Laboratory Range (LR) - 56.6 - 116.03 Level 2: MPI 292-371 - LR 289.5 - 439.98 Level 3: MPI 560-840 - LR Upper Limit (UL) - 926.6 b. Follicle Stimulation Hormone (FSH) - Level 1: MPI 4.21 - 7.02; LR Lower Limit (LL) - 3.02 Level 2: MPI 20.7 - 34.5; LR LL - 17.8 Level 3: MPI 46.4 - 77.4; LR LL - 37.2 c. Luteinizing Hormone (LH) - Level 3: MPI 54.2 - 80.7; LR LL - 51.71 d. Prolactin (PRL) - Level 2: MPI 12.8 -19.0; LR LL - 12.267 e. Human Chorionic Gonadotropin (HcG): Level 1: MPI 3.63 - 10.2; LR LL - 3.5 Level 2: MPI 19.1 - 31.8; LR LL - 18.76 f. Thyroid Stimulation Hormone (TsH): Level 1: 0.330 - 0.649; LR LL - 0.157 Level 2: 4.07 - 9.26; LR LL - 3.94 Level 3: 29.7 - 62.6; LR LL - 24.1 3. The LM confirmed on 7/27/21 at 1:10 pm that the MPI was not followed.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure that Andrology results performed with the American Association of Bioanalysts (AAB) were reviewed and evaluated by the appropriate staff. The findings include: 1. There was no documented evidence the laboratory reviewed: a) Antisperm Antibody IgG+IgA in Andrology & Embryology events S1, S2 2020 and S1 2021. b) Sperm Cell ID and Sperm Viability in Andrology & Embryology event S2 2020. c) Sperm Count Traditional in Andrology & Embryology event S1 2021. 2. The LM confirmed on 7/27/21 at 10:55 am that the LD did not ensure all PT reports were reviewed.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Records (PR) and interview with the Laboratory Manager (LM), the Laboratory Director failed to ensure that the education records were available on the date of the survey. The finding includes: 1. Education records were not available for three of six Testing Personnel (TP). 2. The LM confirmed on 7/27/2021 at 10:00 am that education records were not available.