Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2046030	07/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates	140 Allen Road, Basking Ridge, 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
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 General Supervisor (GS), 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 Viability in Andrology & Embryology event S2 2020. c) Sperm Count Traditional in Andrology & Embryology event S1 2021. 2. The GS #3 listed on CMS form 209 confirmed 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 12:20 pm accuracy of the PT results were not verified
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have all procedures needed for Endocrinology tests from 11/27/18 to the date of the survey. The findings include: 1. The laboratory failed to have a procedure for: a. Verification of new lots of reagents and controls before they were put in use. b. Validation of new instruments or procedures c. Verification of reference ranges 2. The GS #3 listed on CMS form 209 confirmed on 7/27/21 at 1:50 pm that the laboratory did not have the above procedures.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the temperature logs and interview with the General Supervisor (GS), the laboratory did not document corrective action taken when the Room Temperature (RT) and Humidity (HU) was out of range in June and July 2021. The findings include: 1. A two month review of the RT and HU log revealed that the temperature was outside the established range as below: a. June 2021: RT and HU - 10 out of 30 days b. July 2021: RT - 25 out of 27 days; HU 27 out of 27 days. 2. There was no documented evidence of Corrective Action (CA) taken. 3. The GS #3 listed on CMS form 209 confirmed on 7/27/21 at 10:30 AM the laboratory did not document CA when RT and HU were out of range.
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 surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Endocrinology and Immunology tests on the Cobas e801 analyzer from November 2020 to the date of survey. The findings include: 1. There was no documented evidence the LD reviewed or approved the PS. 2. There was no documentation which stated the PS were acceptable. 3. There was no documented evidence that validation was performed for reference ranges used on final reports 4. There was no documented evidence the Laboratory Information System (LIS) was verified. 5. Accuracy results for ACOV2 were not acceptable. EP evaluator used for Accuracy stated: a. Agreement - 41.6% b. Positive Agreement - 18.2% c. Symmetry test FAILS d. Cohen's Kappa 11.3% (Kappa > 75% indicates high agreement) e. Method Comparison results: 45 out of 77 samples failed There was no evidence of corrective action, but ACOV2 test was put into use in the laboratory. 6. Method Comparison summary for Human Chorionic Gonadotropin (HcG) Beta revealed 36 out of 40 samples failed, but method was put into use. 7. Progesterone (PR) linearity found in PS records was not adequate to report the Reference Range (RR) found on the Test Report (TR). a. Linearity achieved in PS: 0.3127 - 47.6333 b TR range for Third Trimester: 48.4 - 422.5 8. The GS #3 listed on CMS form 209 confirmed on 7/7/21 at 11:00 am that PS were not adequate.
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 10:45 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 General Supervisor (GS), 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 twenty of thirty one Testing Personnel (TP). 2. The GS #3 listed on CMS form 209 confirmed on 7/27/2021 at 10:00 am that education records were not available.