Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2014945	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates	2 Industrial Way West, Eatontown, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all Testing Personnel (TP) who performed Andrology, Endocrinology and Chemistry Tests participated in the American Association of Bioanalysts (AAB) PT events in the calendar years 2017 and 2018. The finding includes: 1. A review of all PT event revealed that only one out of four TP performed PT events in 2017 and 2018. 2. The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 10:30 am that PT events were not rotated between TP.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain all PT records for Chemistry and Endocrinology tests performed with the American Association of Bioanalysts (AAB) in 2017. The finding includes: 1. The laboratory did not have the work records for PT Q2-2017 Chemistry. 2. The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 10:00 am that all PT records were not maintained.
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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow the CA procedure on one of four TP in 2017 and 2018. The findings include: 1. The CA was not signed by the reviewer. 2. The TP # 2 listed on CMS form 209 confirmed on 10/30/18 at 9:20 am that 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 the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate Chemistry PT results obtained in event Q1 - 2018 from the American Association of Bioanalysts (AAB). The findings include: 1. There was no evidence that the laboratory verified the accuracy of Fertility Endocrinology analytes when the laboratory received an exception code of # (this method was not graded due to an insufficient number of peer respondents): a. Estradiol - Sample 1 and 2 b. Progesterone - Sample 2 2. The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 10:40 am theQ1 - 2018 Chemistry PT results were not reviewed and evaluated.
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: a) Based on surveyor review of the Bio Rad Manufacture Package Insert (MPI) and

	interview with the Testing Personnel (TP), the laboratory failed to follow the MPI for control material used on the Centaur CP in the calendar year 2018. The findings include: 1. The TP stated that the laboratory used the MPI control ranges. 2. A review of Quality Control (QC) documentation revealed QC ranges for Level 3 Prolactin and Human Chorionic Gonadotropin (ThCG) were outside the MPI range. 3. The TP #2 confirmed on 10/30/18 at 11:00 am that MPI was not followed. b) Based on surveyor review of the MPI and interview with the TP, the laboratory failed to follow the MPI for FructoScreen tests from 9/20/16 to the date of the survey. The findings include: 1. The MPI stated: a. Pipette samples and reagents into a well of the Plate but the laboratory did not use a plate. b. Read optical density of wells at 470 nm using a microplate reader but the laboratory did not have a microplate reader. 2. The TP #2 confirmed on 10/30/18 at 11:30 am that MPI was not followed. c) Based on surveyor review of the MPI and interview with the TP, the laboratory failed to follow the MPI for Accubeads tests from 9/20/16 to the date of the survey. The findings include: 1. The MPI stated to count Vial 1 and 2 two times and average if counts were within 10% of each other but the laboratory counted each vial once. 2. The TP #2 confirmed on 10/30/18 at 11:10 am that MPI was not followed
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to put expiration dates on QC material for Chemistry and Endocrinology tests at the time of survey. The findings include. 1) The expiration date of control material shortens once opened. 2) The laboratory did not put expiration dates on Bio Rad Lyphochek Immunoassay Plus Control in use. 3) The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 11:10 am the laboratory failed to put expiration dates on the control material.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control Records and interview with the Testing Personnel (TP), the laboratory failed to document review for evaluating trends and/or shifts for tests performed on the Centaur CP from 9/20/16 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 11:50 am the laboratory did not document all analytic assessment.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR for Chemistry and Endocrinology testing included all required information from 9/20/16 to the date of the survey. The findings include: 1. The FR reviewed did not have the "Test Report Date". 2. The FR reviewed did not have units of measurement for analytes on the FR. 3. The FR reviewed did not have the name of all tests performed and referred to one test as "P". 4. The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 12:10 pm that the laboratory did not have required information on the FR.
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 lack of Performance Specification (PS) records and interview with the Testing Personnel (TP) the Laboratory Director (LD)failed to ensure that PS were performed on FructoScreen tests from 9/20/16 to the date of survey. The finding includes: 1. An accuracy study was not performed. 2. The TP #2 confirmed on 10/30 /18 at 12:00 pm that the LD did not ensure that PS were performed.
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 Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results obtained from the American Association of Bioanalysts (AAB) were reviewed and evaluated by the appropriate staff in the calendar year 2017 and 2018. The finding includes: 1. There was no review of AAB results for Chemistry event Q1 - 2017 and Q2 - 2018. 2. There was no review of AAB results for Andrology event Q2 - 2017. 3.

	The TP #2 listed on CMS form 209 confirmed on 10/30/18 at 10:10 am that the laboratory did not review and evaluate all PT results.
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 the Personnel Records (PR) and interview with the Testing Personnel (TP), The Laboratory Director failed to ensure that two of three TP had appropriate training documented on the Centaur CP Analyzer prior to patient testing from December 2017 to the date of survey. The TP #2 listed on CMS form confirmed on 10/30/18 at 10:20 am that training was not documented.