Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2120264	01/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates	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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain all PT records performed with the American Association of Bioanalysts (AAB) in S2 2018 event. The finding includes: 1. The laboratory did not retain repeat analysis work records to substantiate corrective action taken for failed S2 2018. 2. The TP # 1 listed on CMS form 209 confirmed on 1/23/19 at 12:30 pm that PT repeat records were not retained.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the work records and interview with the Testing Personnel (TP), the laboratory failed to maintain work records with the identity of the personnel who performed Endocrinology testing from 8/29/17 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 1/23/19 at 1:15 pm that identity of personnel was not on the work records.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to identify problems and correct it on FR from 8 /29/17 to the date of survey. The findings include: 1. When result was negative for Antibody IgG and IgA, the laboratory reports as 1.00. 2. The FR for Endocrinology tests had 'Lab Order' on it . 3. The TP # 1 listed on the CMS form 209 confirmed on 1 /23/19 at 1:00 pm that problems on FR were not identified.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 computer records and interveiw with the Testing Personnel (TP), the laboartory director failed to ensure that all TP were trained for the services offered from 8/29/17 to the date of survey. The finding includes: 1. The TP # 1 listed on the CMS form 209 was trianed on how to retrive date from back up system. 2. The TP # 1 stated on 1/23/19 at 1:15 pm that she was not trained on how to retrieve data.