Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2101776	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates	731 Alexander Road, Princeton, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of the Final Report and interview with the Testing Personnel (TP), the laboratory failed to ensure that quality systems for the postanalytic phase of Hematology testing were monitored from 8/7/17 to the date of the survey. 1. The laboratory did not ensure positive patient identification. Cross Refer D 5805.
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, review of the personnel files and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on the Technical Supervisor (TS) in the calendar year 2017 and 2018. The TP #1 listed on CMS form 209 confirmed on 7/31/19 at 10:00 am that a CA was not performed on the TS.
D5789	TEST RECORDS

	CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to retain the number of White Blood Cells (WBC) counted used in the calculation of the WBC percentage for Semen tests from 8 /2/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 7/31/19 at 11:00 am that records of all patient testing were not retained.
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 Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the FR included the requirements for positive patient Identification (ID) from March 2019 to the date of the survey. The finding includes: 1. A review of ten FR revealed that eight of ten patients' name, date of birth and last 4 digits of the social security number were not from the patient who provided the sample. 2. This was a repeat citation on which The Plan of Correction stated "The new EMR platform has been modified to allow the final semen analysis report to reflect solely the male partner's information when specified. We are now able to satisfy the requirements set forth." 3. The TP #1 of the CMS form 209 confirmed on 7/31/19 at 1:30 pm that the laboratory did not ensure positive patient ID.