Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2046030	01/08/2025
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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the General Supervisor (GS), the laboratory failed to perform correlation studies for Endocrinology tests performed on the Roche e801 analyzers twice per year from 7/21 /21 to the date of the survey. The GS confirmed on 1/8/25 at 11:00 am that the laboratory did not perform a correlation study twice a year.
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 (TL), Monthly incident reports, Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory did not document corrective action taken when the room humidity for zone 1 was out of range from 1/15/24 through 1/23/24. The findings include: 1. The PM states "if humidity out of range for more than 3 days in a row, a humidifier or dehumidifier may be required, enter into incident report." 2. The humidity for zone 1 room humidity was out of range from 1/15/24 to 1/23/24. 3. Zone 1 humidity was only mentioned once on the andrology incident report and did not state if corrective action was taken and if the issue was resolved. 4. The GS confirmed on 1/8/25 at 11: 00 pm, the laboratory did not document corrective action taken.