Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1064315	01/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates Of Michigan	130 Town Center Drive Suite 106, Troy, MI	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on record review and interview with the Phlebotomy Personnel, the laboratory failed to ensure blood collection tubes had not exceeded their expiration dates for 515 tubes available for use. Findings include: 1. The surveyor observed the phlebotomy room on 1/9/24 at 9:11 am and saw the following expired blood collection tubes: a. Five packs (500 tubes) of tiger top serum separator vacutainer tubes expired on 8/31 /23. b. Eight individual tiger top serum separator vacutainer tubes in the phlebotomy trays expired on 8/31/23. c. Seven pink top EDTA anticoagulant vacutainer tubes in the phlebotomy trays expired 11/30/23. 2. An interview on 1/9/24 at 9:31 am with the Phlebotomy Personnel confirmed the tubes listed above had exceeded expiration dates.
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 record review and interview with the Technical Supervisor, the laboratory failed to include the name and address of the laboratory where the test was performed for 1 (Patient #6) of 10 patient test reports reviewed. Findings include: 1. A review of 10 patient test records revealed Patient #6 had testing ordered for "hCG, total beta" on 10/3/22. Patient #6 received testing at a reference laboratory and the results were entered into the laboratory information system. The test report generated by the laboratory did not include the name and address of the reference laboratory. 2. An interview on 1/9/24 at 2:45 pm with the Technical Supervisor confirmed the laboratory failed to include the name and address of the reference laboratory on the test report.