Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1064315	08/19/2025
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
D0000	A recertification survey was performed on August 19, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) with the 493.1240 Condition: Preanalytic systems.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review, observations, and interviews, the laboratory failed to solicit written or electronic order authorization within 30 days of oral requests for testing (refer to D5303), failed to include the patient's full name or unique patient identifier on the test request (refer to D5305), failed to follow its written policies and procedures for specimen labeling to include the full patient name (refer to D5311 A), and failed to follow its written policies and procedures for specimen labeling (refer to D5311 B).
D5303	TEST REQUEST CFR(s): 493.1241(b) (b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

	This STANDARD is not met as evidenced by: . Based on record review and interview with clinic staff, the laboratory failed to solicit written or electronic order authorization within 30 days of oral requests for testing for two (Patients 4 and 8) of 10 patient test requests reviewed. Findings include: 1. A review of patient test requests for the following patients revealed a lack of documentation of test request from an authorized person: a. Patient 4 received Follicle-Stimulating Hormone, Estradiol, and Luteinizing Hormone testing on 4/11/24. b. Patient 8 received Progesterone, Beta-Human Chorionic Gonadotropin, and Estradiol testing on 3/27/25. 2. An interview on 8/19/25 at 11:31 am with clinic staff confirmed the patients listed above did not have documentation of an authorized person requesting the testing performed and revealed the laboratory's process had been to receive orders verbally.
D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: . Based on record review and interview with clinic staff, the laboratory failed to include the patient's full name or unique patient identifier on the test request for one (Patient 7) of 10 patient test requests reviewed. Findings include: 1. A review of Patient 7's test request for semen analysis, performed on 12/19/24, revealed only a first name and date of birth were included. 2. An interview with clinic staff on 8/19/25 at 11:31 am confirmed the test request for Patient 7 did not have the patient's full name or unique patient identifier.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

	This STANDARD is not met as evidenced by: . A. Based on record review, observation, and interview with phlebotomy staff, the laboratory failed to follow its written policies and procedures for specimen labeling to include the full patient name for one of four patient blood specimens observed in the phlebotomy area. Findings include: 1. A review of the laboratory's procedure titled "Phlebotomy Unit Responsibilities" revealed a section stating, "When a patient is ready to have their blood drawn, the phlebotomist escorts the patient to the phlebotomy lab. There, the phlebotomist verifies the lab order and patient's name. The phlebotomist then has the patient verify that all informaiton on the bar code label is correct (i.e. name, SSN, birth date, and today's date). After verification, a gold top serum separator vaccutainer tube (SST) is labeled in pen with the patient's first and last name. Blood is obtained by venipuncture, and the appropriate patient bar code label is placed on the SST. The patient is then asked to verify that their tube was labeled correctly."[sic] 2. The surveyor observed the phlebotomy area on 8/19/25 at 9:05 am and saw four blood specimen tubes. One of the specimens was labeled with a first name only. 3. An interview on 8/19/25 at 9:05 am with phlebotomy staff revealed the specimen labeled with a first name only was to have testing related to an exposure performed. B. Based on record review, observation, and interview with the technical consultant, the laboratory failed to follow its written policies and procedures for specimen labeling for two vacutainers specimen tubes (one with two patient names and one with the patient name covered by a white sticker) observed. Findings include: 1. A review of the laboratory's procedure titled "Phlebotomy Unit Responsibilities" revealed a section stating, "When a patient is ready to have their blood drawn, the phlebotomist escorts the patient to the phlebotomy lab. There, the phlebotomist verifies the lab order and patient's name. The phlebotomist then has the patient verify that all information on the bar code label is correct (i.e. name, SSN, birth date, and today's date). After verification, a gold top serum separator vaccutainer tube (SST) is labeled in pen with the patient's first and last name. Blood is obtained by venipuncture, and the appropriate patient bar code label is placed on the SST. The patient is then asked to verify that their tube was labeled correctly."[sic] 2. The surveyor observed the phlebotomy area on 8/19/25 at 9:05 am and saw a rack of unused vacutainer tubes near the phlebotomy chair. In the rack, one tiger-top serum separator tube was noted to have a white label. Closer inspection of the tube revealed the white label was placed overtop of the label provided by the manufacturer. A patient's name was visible underneath the white label, written on the label provided by the manufacturer. The surveyor also observed a rack near the centrifuge with blood specimens collected and another unused tiger-top serum separator tube with a white label on it over the manufacturer label. This tube had a white label with one patient's name on it, but underneath that label, the manufacturer's label was visible and showed another patient's name. 3. An interview on 8/19/25 at 9:09 am with the technical consultant confirmed the tubes were available for use and the laboratory had been labeling patient tubes prior to collection, not adhering to the process in the procedure listed above.