Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2046784	02/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Medicine Associates Of New York	430 Albee Square Fl 2, Brooklyn, NY	

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
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: Based on direct observation as well as interview with Processing Personnel (PP), the laboratory failed to ensure urine specimens were labeled with distinct identifying indicators including patient name or unique identifier to distinguish between specimens. FINDINGS: 1. The PP informed the surveyor that patient urine specimen containers were labelled in ink with patient's first name, last initial, and no other unique identifiers. Urine specimen containers were subsequently decanted into Aptima tubes featuring a printed label including unique patient identifiers. 2. It was observed that urine container label patient information was smudged or illegible for several of the specimens and the patient's name could not be positively identified. 3. The PP confirmed the findings on February 25th, 2025, at 12:00 P.M.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities.

	This STANDARD is not met as evidenced by: Based on review of incident reports, lack of corrective action records as well as interview with the Laboratory Director (LD), the laboratory failed to perform and document corrective action to prevent recurrence of problems. FINDINGS: 1. On January 28th, 2025, and January 30th, 2025, three incident reports were created by Testing Personnel (TP) to address mislabeling of patient specimens during specimen processing. 2. Approximately six patients were potentially affected by the respective incidents. 3. There was no documentation of subsequent corrective action performance for the respective incidents. 4. The LD confirmed the findings on February 25th, 2025, at 12:00 P.M.