

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2216278	(X3) Date Survey Completed 06/04/2024
Name of Provider or Supplier Reproductive Medicine Associates Of New York At	Street Address, City, State 360 North Bedford Road, Mount Kisco, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory analyzer instrument records, as well as interview with the Laboratory Director (LD), the laboratory failed to retain linearity study documentation. FINDINGS: 1. According to the LD, linearity studies were performed for July 2023 and February 2024. The linearity study documentation was reviewed, signed during the QA reviews. 2. The respective linearity documentation was not available for review. 3. The LD confirmed the findings on June 4th, 2024, at 12:30 P. M.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of twice year verification records, the current, approved standard operating procedures, as well as interview with the LD, the laboratory failed to perform twice year verification for the Fructoscreen panel. FINDINGS: 1. There was no documentation of Fructoscreen panel twice year verification performance for calendar years 2022 and 2023. 2. The LD confirmed the findings on June 4th, 2024, at 12:30 P.M.</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the Endocrine Laboratory Procedure Manual, Section 2, as well as interview with the LD, the laboratory failed to perform linearity studies for all analytes. FINDINGS: 1. The current, approved standard operating procedures included instructions for linearity studies to be performed on all analytes not exceeding 6 calendar months. 2. There was no documentation of linearity performance for the first six months of 2023. Approximately 569 patients were tested during this period. 3. The LD confirmed the findings on June 4th, 2024, at 12:30 P.M.