| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 33D2082475 | 04/27/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Reproductive Medicine Associates Of New York Llp | 200 West 57th Street 9th Floor, New York, 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 |
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| **D2005** | ENROLLMENT<br>CFR(s): 493.801(a)(4)<br><br>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor's review of the American Association of Bioanalysts (AAB) proficiency testing ( PT) records an and interview with the laboratory director/testing person, the laboratory failed to have the AAB PT test results released to New York State Department of Health (NYSDOH), Physician Office Laboratory Evaluation Program (POLEP) and Center for Medicare and Medicaid Services (CMS) in the calendar years 2019 and 2020. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of laboratory Quality Control (QC) records, laboratory procedures for sperm viability and fructose screening and interview with the laboratory director/testing person, the laboratory failed to perform and document the |

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| | positive and negative controls and reactivity for the stains used sperm viability testing and fructose screening in calendar years 2019 and 2020. FINDINGS 1. The laboratory director/testing person confirmed on April 27, 2021 at 11:00 AM that the quality control records for the sperm viability and fructose screening were not available for review at this survey. 2. The FertiPronv sperm viability procedures utilizes stain A 20 ml of 1% Eosin Y in saline and stain B 30 ml of 10% Nigrosin in saline for sperm viability procedure. a. The laboratory did not record the reactivity results as non-viable sperm stained and viable does not stain b. Approximately 50 patient's sperm specimens were tested and reported for sperm viability for the calendar years 2019 and 2020. 3. The Fructose Screening procedure utilizes Indole stain to indicate if fructose is present in seminal plasma of the sperm. a. The laboratory did not record the control results (positive-yellow-orange/negative- no color) each day of patient testing. b. Approximately 30 patient's sperm were tested and reported for fructose in the calendar years 2019 and 2020. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of laboratory policies and procedures, lack of laboratory Quality Control (QC) records and an interview with the laboratory director/testing person, the laboratory director failed to ensure that all components of quality control for sperm viability and fructose screening were maintained to provide quality laboratory services. Refer to: D5449 |