| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D0909802 | 04/25/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Reproductive Medicine Associates Of New York | 635 Madison Avenue 10th 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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| **D0000** | An announced CLIA exempt-state validation survey was performed at the Reproductive Medicine Associates of New York on April 25, 2023, by two CMS New York CLIA Branch Location federal surveyors. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory is in compliance with condition-level CLIA requirements. The standard-level deficiencies are cited as the following: |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of quality control (QC) records and the endocrinology laboratory procedure manual, lack of documentation and staff interview the laboratory failed to |

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| | establish a corrective action policy when quality control results failed to meet the laboratory's criteria for acceptability for all analytes in the endocrinology section of the laboratory. Findings include: 1. During a QC record review on April 25, 2023 at approximately 12:05 PM in the endocrinology section of the laboratory for analyte AMH serum control values, revealed during May 2021 dates 05/15/21-05/29/21 the QC was out of range 6 out of 16 days: a. 5 of 16 days 1 out of 3 QC was out of range. b. 1 of 16 days 2 out of 3 QC was out of range. 2. The surveyor requested the laboratory quality control corrective action measure policy. The laboratory director stated "We say 2 out of 3 QC is acceptable for patient results but we do not state this in our policy". 3. During the exit interview at 2:55 PM, the above findings we confirmed. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory quality assessment (QA) procedure, endocrinology procedure, and interview with the laboratory director (LD) and the director of compliance, the laboratory failed to have a system that twice a year evaluates and defines the relationship between two of two Cobas 600s in 2021 to 2022. Findings Include: 1. The Andrology / Endocrinology Quality Assurance Plan, 2. Analytical Monitors, E. Comparison of Test Results states, "When the laboratory performs the same test at multiple testing sites or multiple instruments, the laboratory must at least twice a year evaluate the relationship between test systems". 2. On the day of the validation survey performed on April 25, 2023, a review of the QA and endocrinology procedures revealed, the laboratory did not establish criteria for the accepted ranges for the comparison for two of two Cobas 600s. 3. Review of the Cobas 600s comparison documents revealed the laboratory did not evaluate the relations between both Cobas Endocrinology analyzers in 2021 and 2022. 4. Comparison Studies were performed on February 16, 2021 and July 15, 2022. 5. The LD and director of compliance confirmed the findings above on 04/25/2023 around 1: 25 pm. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on a review of quality control (QC) records, staff interview, and lack of corrective action documentation the laboratory failed to document corrective action measures when the progesterone (PRG) analytes low control was out of range 55 of 61 days from the month of March 2021 to April 2021. Findings Include: 1.The Interassay Variability Serum Control Report Serum Control Bio-Rad Low Control Range (0.508- 0.877), Lot# 40380 - Exp. 08/31/21: a. March 2021 - 28 of 31 days the low control was greater than 0.877. b. April 2021 - 27 of 29 days the low control was greater than 0.877. c. The low control displays a trend of repeatability greater than 0.877. 2. The March/April 2021 Interassay Variability Serum Control Values log under the Comm. Column states, "1 out of 3", with no additional information provided. The log was signed for review 04/1/21. 3. On April 25, 2023, at approximately 2:30 PM, during the exit interview with the laboratory director, the surveyor reviewed the chart of the repeated trend of the low control and the laboratory director confirmed the laboratory did not identify or reconcile the out-of-range trend. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of quality control (QC) records, meeting minute records, and laboratory quality assessment policy, the laboratory failed to follow their established policy for "Monitoring of Operational Parameters Section Quality Control Monitors Subsection 'Identify, Reporting, and Reconciling Trends, Drifts & Bias". Findings Include: 1. The policy states "Report trending, drifting, bias and unreconciled quality control events on the Problems Encountered report form." 2. Monthly Review of Laboratory: a."Dates of Meeting April 6, 2021 - New Topics to be Discussed "did not include documentation of low-range trend of QC for progesterone analytes with results greater than 0.877 28 out of 31 days for March 2021. b. "Dates of Meeting May 4, 2021 - New Topics to be Discussed "did not include documentation of low-range trend of QC for progesterone analytes with results greater than 0.877 27 out of 29 days for April 2021. 3. On April 25, 2023, around 2:35 PM, during the exit interview the laboratory director confirmed the laboratory should document trends for quality control. |