

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2208444	<b>(X3) Date Survey Completed</b>  08/19/2025
<b>Name of Provider or Supplier</b>  Reproductive Medicine Associates Of	<b>Street Address, City, State</b>  4510 Executive Dr Ste 150, San Diego, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2014</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b></p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2022-2025 laboratory proficiency testing reports from CMS (Report 155D, Individual Laboratory Profile) and AAB/MLE (American Association of Bioanalysts/ Medical Laboratory Evaluation), the lack of laboratory records, and interview with the Technical Consultant (Testing Person-1/Laboratory Supervisor), it was determined that the laboratory failed to maintain copies of all proficiency testing records including Attestation Statements signed by the Laboratory Director and Testing Personnel. Findings included: a. The laboratory participated in AAB/ MLE's proficiency testing program for Estradiol, FSH (Follicle Stimulating Hormone), HCG (Human Chorionic Gonadotropin, pregnancy test), LH (Luteinizing Hormone), Progesterone, Prolactin, TSH (Thyroid Stimulating Hormone), and AMH (Anti-Mullerian Hormone). b. The laboratory failed to have records documenting the handling, preparation, processing, and testing of all proficiency testing samples. c. The laboratory failed to have Roche cobas e411 instrument printouts of results and the AAB/MLE forms for reporting results. d. The laboratory failed to retain AAB/MLE Attestation Statements signed by the Laboratory Director and Testing Person to document that proficiency testing samples were tested by personnel who routinely tested patient specimens. e. The laboratory failed to retain the aforementioned records and documents for all specimen and analytes for all events in 2022-2025. f. The</p>

Technical Consultant affirmed (8/19/25 at 2:30 PM) the aforementioned findings. g. The reliability, quality, and integrity of all results reported for proficiency testing could not be assured. .

**D2104**

**ENDOCRINOLOGY**  
CFR(s): 493.843(d)

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on review of Event1/2025 laboratory proficiency testing reports from CMS (Report 155D, Individual Laboratory Profile) and AAB/MLE (American Association of Bioanalysts/ Medical Laboratory Evaluation) and laboratory records, and interview with the Technical Consultant (Testing Person-1/Laboratory Supervisor), it was determined the laboratory failed to test and report proficiency testing results within the timeframe specified by AAB/MLE. Findings included: a. CMS and AAB/MLE reported scores of 0% in the 1st Event of 2025 for all analytes, as follows: Estradiol FSH HCG Luteinizing Hormone Progesterone Prolactin TSH b. Laboratory proficiency testing records documented the samples were tested after the deadline for reporting results. c. The Technical Consultant affirmed (8/19/25 at 2:30 PM) the aforementioned findings. d. The reliability and quality of results reported during the timeframe February - early May 2025 could not be assured in this Survey. Six patients records randomly selected from this timeframe for review are, as follows: Date Accession # ----- 2/28/25 L5461682233 3/11/25 L5464501340 3/28/25 L5477461744 4/11/25 L5487981872 4/28/25 L5494582926 5 /05/25 L5491731371.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing scores for Event 2/2024 for Estradiol from CMS (report 155D, Individual Laboratory Profile) and AAB/MLE and laboratory records, the lack of records, and interview with the Technical Consultant, it was determined the laboratory failed to verify the accuracy of testing for Estradiol. Findings included: a. The laboratory chose to participate in AAB/MLE's proficiency testing program as the means to fulfill the requirement to verify the accuracy of testing. b. CMS and AAB/MLE reported the unsatisfactory score of 50% for Estradiol. The laboratory reported 1 unacceptable result (\*) out of 2, as follows: PT Sample Lab result Acceptable Range ----- # 6 105\* 15.0 - 28.0 c. The laboratory had no records for alternate means of verifying the accuracy of testing for Estradiol during this timeframe of May - August 2024. d. The Technical Consultant affirmed (8/19/25 at 2:30 PM) the aforementioned findings; and thus, the laboratory's failure to verify the accuracy of testing for Estradiol. e. The reliability and quality of results reported for Estradiol during the timeframe May - August 2024 could not be assured in this Survey. Patients records selected at random

for review are, as follows: Date Accession # ----- 6/03/24  
L5337072106 6/25/24 L5348441168 7/11/24 L5352511189 7/22/24 L5358421122 8  
/07/24 L5367622197 8/30/24 L5374511170 .

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on observation of the Roche cobas e411 chemistry analyzer (serial number 870101), review of laboratory records for calibration verification, the lack of laboratory records, and interview with the Technical Consultant (Testing Person-1 /Laboratory Supervisor), it was determined tha laboratory failed to verify calibrations at least once every 6 months. Findings included: a. The Roche e411 tested for serum HCG, Prolactin, E2 (Estradiol), PRG (Progesterone), Luteinizng Hormone, TSH (Thyroid Stimulating Hormone), FSH (Follicle Stimulating Hormone) and AMH (Anti-Mullerian Hormone). The laboratory reported 10,000 results annually (CMS116 CLIA Application, 8/10/25). b. Laboratory records documented calibration verifications were performed, as follows: Date ----- 6/13/22 11/15/22 \* 6/13/23 12/19/23. \* 7/30/25 c. The laboratory failed to verify calibrations at least once before June 2023 and before June 2025. d. The Technical Consultant affirmed (8/19/25 at 2: 30 PM) the aforementioned findings. e. The reliability and quality of results reported in May 2023 and June 2025 could not be assured in this Survey. Three patient test records randomly selected from June 2025 for review are, as follows: Date Accession # Analytes ----- 6/05/25  
L5508291057 E2, PRG, HCG, TSH 6/17/25 L5511731823 E2, FSH, LH, PRG, TSH 6 /30/25 L5514341492 E2, FSH, LH, PRG .