

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2292742	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Reproductive Medicine Associates	Street Address, City, State 1320 El Capitan Dr Ste 410, Danville, CA	
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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedure, proficiency testing (PT) records, lack of corrective action documentation, and an interview with the testing personnel (TP) on March 4 , 2026, it was determined that the laboratory failed to perform and document a corrective action for any analyte that achieved an unsatisfactory score of less than 100 percent. The findings include: 1. The laboratory failed to follow their established and approved policy and procedure for PT to perform and document a corrective action report for any unsatisfactory scores obtained. 2. The laboratory was enrolled with the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) PT program and obtained an unsatisfactory score of the following: a. 50% Sperm count (Qualitative), second event of 2023 (Q2-2023), b. 50% Sperm count (Qualitative), first event of 2024 (Q1-2024), and c. 80% Sperm cell ID, first event of 2025 (Q1-2025). 3. The surveyor's review of the PT documentation revealed that no corrective action report was available for review at the time of the survey. 4. The TP affirmed by an interview on March 4, 2026, at approximately 10:10 a.m., that the corrective action documentation could not be located for the unsatisfactory proficiency testing scores obtained in the Q2-2023, Q1-2024 and Q1-2025 events. Thus, the quality and reliability of patient tests reported cannot be assured. 5. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 120 Semen analysis tests annually, including the time when unsatisfactory PT scores were received and no corrective action was available for review.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p>

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing documentation, lack of corrective action reports and an interview with the testing personnel on March 4, 2026, the laboratory director is herein cited for failing to ensure that the laboratory followed an established policy and an approved corrective action plan when any proficiency testing result obtained are found to be unacceptable or unsatisfactory. See D5221.