

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0602416	(X3) Date Survey Completed 10/01/2025
Name of Provider or Supplier Sperm Bank Of California	Street Address, City, State 2115 Milvia St, 2nd Flr, Berkeley, 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
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 observation of Makler Chambers, review of laboratory test records for Semen Analysis and 2024-2025 proficiency testing reports from AAB/MLE (American Association of Bioanalysts/Medical Laboratory Evaluation), and interview with laboratory personnel, it was determined that the laboratory failed to verify the accuracy of testing for Sperm Count and Sperm Motility. Findings included: a. The laboratory performed Semen Analysis using the Makler Chamber to manually count, calculate, and report results for Sperm Count and Sperm Motility. b. The laboratory participated in AAB/MLE's proficiency testing program titled, "Embryology, Andrology & Fetal", as the means to fulfill the requirement to at least twice annually verify the accuracy of testing. c. Sperm Count 1. AAB/MLE reported unsatisfactory scores of 50% due to the laboratory's 1 unacceptable result (*) out of 2, for Sperm Count, as follows: Event PT Lab Mean/ Sample result Intended Results ----- 2, 2024 7 22 * 39.7 1, 2025 1 20* 38.7 d. Sperm Motility 1. AAB/MLE reported the unsatisfactory score of 0% due to the laboratory's 2 unacceptable results (*) out of 2, for Sperm Motility, as follows: Event PT Lab Mean/ Sample result Intended Results ----- 1, 2025 1 37 * 21.5 2 27* 10.8 e. The laboratory had no records for alternate methods of verifying test accuracy for Sperm Count and Sperm Motility. f. The Laboratory Executive Director /Administrator affirmed (10/01/25 at 12:30 PM) the aforementioned findings. g. And thus, the reliability and quality of results reported could not be assured during this Survey for Sperm Counts and Sperm Motility. The laboratory affirmed (by Email, 10 /03/25 at 11:31 AM) reporting 585 Semen Analyses during the timeframe 5/06/24 to 9</p>

/13/25. Semen Analysis laboratory reports selected for review are, as follows: Date
Acc # ----- 5/06/24 95620 6/05/25 95824 9/11/25 95872 .