

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0969849	(X3) Date Survey Completed 12/07/2021
Name of Provider or Supplier Zouves Fertility Center	Street Address, City, State 1241 E Hillsdale Blvd Ste 100, Foster City, 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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from the CMS 96 Report, laboratory proficiency reporting from AAB (American Association of Bioanalysts), and an interview with laboratory personnel (LP) on 12/7/2021 between 2:30 p.m. and 4:30 p.m., it was determined that there were unacceptable (below 80 %) proficiency testing (PT) results for Sperm Morphology and Sperm Motility (general category of Hematology). Findings include: 1. On 12/7/2021, an inspection was conducted between 2:30 p.m. and 4:30 p.m. 2. During a review of the laboratory documentation from AAB (agency providing the proficiency specimens), it was noted at approximately 3:30 p.m. that there were unacceptable PT results for Sperm Morphology and Sperm Motility from cycle S2. 3. The findings were as follows: Cycle S2 2020 Andrology and Embryology /Hematology Analyte: Sperm Morphology (1/2 unacceptable for each) Sperm Morphology, Digital Slide Result Grading Range 16 0-13 Analyte: Sperm Motility (1 /2 unacceptable for each) Sperm Motility Result Grading Range 31 34-58 4. The LP affirmed the unacceptable results listed above.</p>