

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0971042	(X3) Date Survey Completed 08/06/2019
Name of Provider or Supplier East Bay Fertility	Street Address, City, State 123 N 500 E, Payson, UT	
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 lack of documentation, SQA-V semen analysis instrument manufacturer's instructions, and interview with staff, the laboratory failed to verify semen analysis test accuracy at least twice a year for 2 of 2 years reviewed, 2017 and 2018. The laboratory performed approximately 3 semen analysis per week. Findings include: 1. The laboratory failed to document twice annual test verification for sperm count, motility, abnormal sperm morphology. 2. SQA-V manufacturer instructions included instructions for the laboratory to enroll in College of American Pathology semen analysis proficiency testing at least twice annually. 3. In an interview conducted on 08/06/2019 at approximately 3:30 P.M., the laboratory manager confirmed the laboratory did not participate in a proficiency testing program that included the measured and assessed portions of the semen analysis reported by the SQA-V instrument.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on manufacturer's operator's manual review, lack of documentation and interview with staff, the laboratory failed to follow instructions to perform testing within the range of 22-26 degrees C for semen analysis performed using the SQA-V semen analysis instrument. The laboratory performed 3 semen analysis per week. Findings include: 1. The SQA-V manufacturer's operator's manual stated testing temperature range was 22-26 degrees C, 2, The laboratory failed to monitor room temperature each day of testing to ensure testing was performed within the 22-26 degree temperature range. 3. In an interview conducted on 08/06/2019 at approximately 3:45 P.M. staff stated the laboratory did not monitor room temperature each test day.