Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0971042	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
East Bay Fertility	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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel, proficiency samples are tested twice, patient samples are tested once. Findings include: 1. Proficiency testing record review included instrument printouts for each proficiency sample labeled 'test 1' and 'test 2'. 2. In an interview on 9/8/2021 at approximately 12:35 pm, testing personnel 1 (TP 1) confirmed that patient samples are tested once, but proficiency samples are tested twice.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel, no investigation, remedial action, or training took place after unsatisfactory performance on proficiency testing. The laboratory performs approximately 200 semen analysis tests annually.

	Findings include: 1. Document review of proficiency testing results for CAP Sem-A proficiency testing event of 2020 included an unacceptable result for 1 of 2 proficiency test samples. 2. Review of proficiency testing documentation lacked investigation into proficiency testing failure, remedial action, or subsequent training. 3. In an interview on 9/8/2021 at approximately 12:20 pm, TP 1 confirmed that there was no investigation or corrective action taken after proficiency testing failures.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on document review and interview with testing personnel, no written policy or procedure to monitor, assess, or correct problems exists. Findings include: 1. Document review did not include a policy or procedure for Quality Assessment. 2. In an interview on 9/8/2021 at approximately 1:15 pm, TP 1 confirmed that no policy or form or process is in place for ongoing monitoring, assessment, or correction of problems is in use.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on document review and interview with testing personnel, changes to procedure were not documented, approved, signed or dated by the laboratory director before use. Findings include: 1. Procedure for performance of semen analysis on the SQA- V Gold instrument most recent signature from laboratory director was 05/2011. 2. Procedure for performance of semen analysis on the SQA-V Gold instrument lacks instructions for instrument maintenance. 3. Procedure for performance of semen analysis on the SQA-V Gold instrument states 3 levels of quality control (QC) will be run daily. 4. Record review showed 2 levels of control were run each day of testing. 5. In an interview on 9/8/2021 at approximately 12:00, TP 1 confirmed that procedure for semen analysis on the SQA-V Gold instrument is not followed and lacks instructions for instrument maintenance.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with testing personnel, the laboratory failed to maintain conditions for reliable test system operation as provided by the manufacturer. Findings include: 1. Manufacturer user guide states maximum operational humidity is 80%. 2. Record review lacked documentation of humidity. 3. Manufacturer user guide states system is calibrated to measure semen samples at 20-25C. 4. Record review included a room temperature log with a stated acceptable range of 71.6-78.8F. 5. Record review included 86 instances in 2021 of temperatures outside of the stated acceptable range. 6. Record review lacked documentation of corrective action for out of range room temperatures. 7. Record review included patient testing performed on days that room temperature was recorded out of acceptable range. 8. Interview with TP 1 confirmed that room temperature was recorded from a clock in the testing laboratory. 9. In an interview on 9/8/2021 at approximately 12:25, TP 1 confirmed that room temperature was recorded from a clock in the testing laboratory, no corrective action was taken and testing was performed if the room temperature was out of range, and humidity was not monitored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and interview with testing personnel, reagents, control material, and supplies were used past their expiration date. Findings include: 1. UA Multistix (Uriscan) were found in a drawer with an expiration date of 2012-06-30. 2. Clay Adams Sedi-stain was found in a drawer with an expiration date of 2019-06-05. 3. Clay Adams Sedi-stain was found in a drawer with an expiration date of 2015-09-25. 4. Nitrazine paper was found in a drawer with an expiration date of Sep 2005. 5. KOH reagent was found in a drawer with an expiration date of 2018-11-06. 6. Zymot multi sperm separation device was found in a drawer with an expiration date of 2021-04-28. 7. Quality control (QC) container states that QC material expires 90 days after opening. 8. QC containers lacked an open date, as well as no date in use written in QC log. 9. In an interview on 9/8/2021 at approximately 1:05 pm, TP 1 confirmed that QC was not labeled with open date or written in log, and expired reagents and supplies were kept in a drawer.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel, maintenance on the SQA-V Gold instrument was not documented. Findings include: 1. SQA-V Gold user guide contains requirements for daily and weekly cleaning. 2. Record review lacked documentation of performance of maintenance on SQA-V Gold instrument. 3. In an interview on 9/8/2021 at approximately 1:00 pm, TP 1 confirmed that maintenance is performed according to manufacturer's user guide, but not documented.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel, two control materials of different concentrations were not assayed each day of patient testing. Findings include: 1. Record review for 3/15/2021 included only a negative control result. 2. Patient record review for patient ID 1001 included testing results performed on 3/15 /2021. 3. In an interview on 9/8/2021 at approximately 1:10 pm, TP 1 confirmed that only a negative control was assayed on 3/15/2021.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories performing moderate complexity testing was not met. The laboratory failed to properly perform or evaluate proficiency testing (see D2010 and D2128), failed to evaluate competency of testing personnel (see D6054), failed to document or remove expired supplies and reagents from the laboratory (see D5417), failed to review and update testing procedures (see D5407), failed to properly evaluate and document conditions for testing (see D5413 and D5433), failed to properly perform QC (see D5447), and failed to document or assess quality of laboratory operations (see D5291).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on document review and interview with testing personnel, evaluation and documentation of performance of testing personnel was not performed annually. Findings include: 1. Document review included competency evaluations for testing personnel dated in 2019. 2. Document review did not include competency evaluations for testing personnel in 2020 or 2021. 3. In an interview on 9/8/2021 at approximately 11:30 am, TP 1 confirmed that no competency evaluations have been performed since 2019.