Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2246408	07/14/2026
Name of Provider or Supplier	**Street Address, City, State**	
Empower Fertility Labs, Llc	427 W Pueblo St Ste C, Santa Barbara, 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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on the lack of a policy and procedure for retention requirements and an interview with the laboratory personnel (LP) on July 14, 2026, it was determined that the laboratory failed to establish a policy for retention requirements applicable to Hematology as required in CFR 493.1105(a). The findings include: 1. The laboratory lacked a retention policy and procedure for all types of records applicable to Hematology as required in CFR 493.1105(a). 2. The LP confirmed in an interview on July 14, 2026, at approximately 9:45 a.m. that the laboratory lacked the retention policy and procedure to store all types of records as required. 3. According to the laboratory testing declaration form (Lab-144) submitted at the time of the survey, the laboratory processed and reported approximately 180 Hematology samples annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedure, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of corrective action documentation, and an interview with the laboratory personnel (LP) on July 14, 2026, it was determined that the laboratory failed to perform and document a corrective action for the Sperm Motility test that achieved an

	unsatisfactory score during the second event of 2024 (Q2-2024) and first event of 2026 (Q1-2026). The findings include: 1. The laboratory's policy and procedure for proficiency testing stated that all scores that are less than 100% should have a corrective action. However, the laboratory failed to provide documentation of correction. 2. The laboratory was enrolled with AAB-MLE PT program and obtained an unsatisfactory score of 0% for the Forward Progression under Sperm Motility test in both the Q2-2024 and Q1-2026 events. 3. During an interview on July 14, 2026, at approximately 9:57 a.m., the LP affirmed that there was no corrective action documentation available for review at the time of the survey. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 180 Sperm analysis tests annually, including the time when unsatisfactory PT scores were received and no corrective action was performed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's quality control (QC) documentation, policy and procedure, six patient records dated from 01/03/2024 to 06 /05/2026, and an interview with the laboratory personnel (LP) on July 14, 2026, it was determined that the laboratory failed to perform and document QC prior to patient testing on October 7, 2025. The findings include: 1. Review of the laboratory's QC documentation and policies and procedures showed that QC must be performed, documented and acceptable prior to patient testing. This was not followed specifically on October 7, 2025 for the Sperm analysis test. 2. The surveyors reviewed six patient records dated from 01/03/2024 to 06/05/2026 and found one record (Accession #10312) in the Sperm analysis test that was performed outside the QC validity on October 7, 2025. 3. The LP confirmed in an interview on July 14, 2026, at approximately 10:05 a.m., that the one patient sample tested on October 7, 2025, were performed beyond QC validity and that no repeat testing or corrective action was documented. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory tested and reported approximately 180 Sperm analysis tests annually. .
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of six patient test reports dated from January 3, 2024,

	to June 5, 2026, and an interview with the laboratory personnel (LP) on July 14, 2026, it was determined that the laboratory failed to address errors in patient records prior to finalizing reports. The findings include: 1. The surveyor reviewed six patient records and identified one record with a discrepancy in the accession number between the Semen Analysis Worksheet and the final report reviewed in the nABLE IVF electronic record. a. For patient M3515, tested on February 3, 2026, the accession number recorded in the nABLE IVF electronic record was 003301, while the worksheet documented the accession number as 003303. b. No amendment report or corrective action documentation was available at the time of the survey. 2. The LP confirmed in an interview on July 14, 2026, at approximately 10:05 a.m. that the laboratory failed to address the discrepancy in the accession number between records prior to finalizing reports. The LP further stated that the nABLE IVF electronic record system automatically generates accession numbers, and the number cannot be edited in the system. 3. According to the laboratory's testing declaration form (Lab-144) submitted at the time of survey, the laboratory performed and reported approximately 180 Sperm analysis tests annually including the time when the discrepancy occurred.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is 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, and an interview with the laboratory personnel on July 14, 2026, this deficiency is cited for the laboratory director for failure to ensure that an approved corrective action plan was followed when proficiency testing results received were unsatisfactory. See D5221
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, errors identified in selected patient test records, and an interview with the laboratory personnel on July 14, 2026, this deficiency is cited for the laboratory director for failing to ensure that the quality control and quality system assessment policy and procedures established were followed. The findings include: 1. The laboratory failed to perform and maintain the quality control documentation on October 7, 2025. See D5481 2. The laboratory failed to ensure that patient information matched across records. See D5821
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel

	responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the lack of a retention policy and procedure, survey findings and an intervie with the laboratory personnel on Juley 14, 2026, the laboratory director is herein cited for failure to ensure that an approved, signed, and dated procedure manual that accurately reflected current laboratory practices was available for all personnel. See D3013.