

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D1043824	<b>(X3) Date Survey Completed</b> 02/18/2025
<b>Name of Provider or Supplier</b> Advanced Fertility Associates	<b>Street Address, City, State</b> 4690 Hoen Ave, Santa Rosa, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2104</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS proficiency testing (PT) records report 150D (CLIA Application and Survey Summary) for 2023 proficiency testing results, the American Proficiency Institute (API) PT report for 2023, and interview with the laboratory director (LD); it was determined that the laboratory failed to return PT results for endocrinology subspecialty for the second quarter event (Q2-2023) to the API testing program within the time frame specified by the program is unsatisfactory performance and results in a score of zero (0) The findings included: 1. The API reported to CMS for Q2-2023 an unsatisfactory score of 0% for endocrinology and HCG PT failure to submit results within the time frame specified by the program. 2. The LD affirmed by interview on the day of the survey February 18, 2025, at approximately 10:50 a.m. that API proficiency testing for Q2-2023 endocrinology and HCG received and unsatisfactory grade of zero (0) for which no corrective action was recorded. 3. Based on the laboratory's annual test volume declaration CMS 116 submitted and signed by the LD on 02/18/2025; the laboratory analyzed and reported approximately 1,350 endocrinology samples including HCG.</p>
<b>D5391</b>	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>(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 preanalytic systems specified at 493.1241 through 493.1242.</p>

This STANDARD is not met as evidenced by:  
Based on the surveyors' review of the laboratory's policies & procedures, five (5) randomly selected patients' test records, and interview with the laboratory director (LD) and testing personnel (TP); the laboratory failed to establish and follow written policies and procedure to assess quality of its preanalytical, analytic, and postanalytic systems. The findings include: 1. The laboratory did not have a system in place to identify problems in the preanalytical, analytic, and postanalytic system such as test request, testing results, and final report. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification, immediate resolution of the problem, and development of policies that will prevent its reoccurrence. 2. The LD and TP on the day of the survey at approximately 11:00 a.m., affirmed that the laboratory did not establish and follow preanalytic, analytic, and postanalytic systems quality assessment policies and procedures. 3. The laboratory's testing declaration form, signed by the laboratory director on 02/18/2025 stated that the laboratory performed approximately 1,525 tests annually.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on the surveyor's observation during the laboratory's tour and interviews with the testing personnel (TP), it was determined that the laboratory failed to label quality control (QC) reagents used in the laboratory to indicate the received date, opening, preparation, and expiration dates when such materials are used. The findings include: 1. Based on the surveyor's observation during the laboratory tour on February 18, 2025, at approximately 11:30 a.m. no received date, opening date, and preparation labels were used or documented for QC reagents used for semen analysis. 2. The laboratory's TP affirmed in an interview conducted on February 18, 2025, at approximately 11:35 a.m. that the QC reagents mentioned in statement #1 were not labeled properly with the received date, opening, preparation, and/or expiration date. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 175 tests for Hematology- semen analysis in which QC reagents were not labeled properly.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

(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 the surveyor's observation during the laboratory tour, examination of laboratory reagents, and interviews with the laboratory's testing personnel (TP); it was determined that the laboratory failed in not using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's observations during the laboratory tour, the laboratory stored one (1) only one available of quality control reagent for semen analysis counting chamber Lot # 045-301, Expiration date 02/09/2025. 2. The TP affirmed on February 18, 2025, at approximately 12:15 p.m. that the laboratory only had one bottle of expired QC reagent for semen analysis as stated in #1 above. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory tested and reported approximately 175 semen analysis annually where expired QC reagent may have been used.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory tour, review of the laboratory's policies and procedure, five (5) randomly selected patient records, and interviews with laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the thermometers used in the laboratory. The findings included: 1. At the time of survey on 2/18/2025, based on the surveyors' observation during the laboratory tour and review of records and documentation at approximately 11:00 a.m.; it was determined that the laboratory failed to perform calibration on the thermometers, both mercury and digital, for the years 2023 and 2024. 2. The LD and TP affirmed on February 18, 2025, at approximately 11:30 a.m. that calibration was missed for the thermometers for the years 2023 and 2024. 3. According to the laboratory's testing declaration submitted by the LD, the laboratory performed approximately 1,525 samples annually for which no calibration for the thermometers used in the refrigerator and freezer where patients' samples and reagents are stored.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory tour, lack of a quality assurance/assessment plan, review of the laboratory's proficiency testing records, policies and procedures, randomly selected patient test records, and interviews with the laboratory director and testing personnel on February 18, 2025, it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Failure to document corrective action for

unsuccessful proficiency testing results. See D2104 2. No policy, procedure, and documentation for quality assessment/assurance. See D5391. 3. Test systems, equipment, instruments, reagent. See D5415 and D5417. 4. Failure to calibrate thermometers used in the laboratory D5429.