

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D0530337	<b>(X3) Date Survey Completed</b>  07/26/2019
<b>Name of Provider or Supplier</b>  Aspire Fertility, DbA Arizona Center	<b>Street Address, City, State</b>  8997 E Desert Cove Ave, Floor 2, Scottsdale, AZ	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2018 and 2019 and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for the regulated analyte, serum hCG, tested in the specialty of Chemistry, which is included in subpart I . Findings include: 1. The laboratory performs patient testing in the sub-specialty of Endocrinology, with an approximate annual test volume of 612. The laboratory was issued a CLIA Certificate of Registration which was effective 6/11/2018. 2. No documentation was presented for review during the survey conducted on July 26, 2019 to indicate the laboratory was enrolled in a CMS-approved PT program for the regulated analyte, serum hCG, listed in subpart I, for which the laboratory performs patient testing. 3. The facility personnel confirmed that the laboratory was not enrolled in a CMS-approved PT program at the time of the survey.</p>
<b>D5217</b>	<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</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on lack of verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of endocrinology testing at least twice annually during 2018. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Endocrinology, with an approximate annual test volume of 612. The laboratory was issued a CLIA Certificate of Registration which was effective 6/11/2018. 2. No documentation was presented for review during the survey conducted on July 26, 2019 to indicate the laboratory verified the accuracy of the following analytes at least twice annually in 2018, which are not included subpart I: Estradiol, Progesterone, and Luteinizing Hormone (LH). 3. The facility personnel confirmed that the laboratory failed to verify the accuracy of the analytes indicated above at least twice annually during 2018.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on review of maintenance documentation for the Vidas analyzer and interview with the facility personnel, the laboratory failed to perform and document monthly function check procedures as required by the manufacturer. Findings include: 1. The laboratory uses the Vidas analyzer to conduct patient testing in the sub-specialty of endocrinology, with an approximate annual test volume of 612. 2. Review of the monthly instrument maintenance logs for the Vidas indicated the laboratory failed to perform and document the monthly QVC in May 2019 as required by the manufacturer. According to the manufacturer, the QVC (Quality Control Vidas) is used to check the pipetting mechanisms and optical system of the analyzer. 3. The facility personnel confirmed that the laboratory failed to perform the QVC in May 2019.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of Quality Control (QC) documentation and interview with the technical supervisor, the laboratory failed to document the acceptability of staining materials used for testing performed in the specialty of Hematology. Findings include: 1. The laboratory performs semen analysis testing in the specialty of Hematology,

with an approximate annual test volume of 125. 2. It is the practice of the laboratory to perform the Stat 3 stain on patient specimens in order to analyze semen morphology. 3. No documentation was presented for review during the survey to indicate the laboratory tested the Stat 3 stain for intended reactivity to ensure predictable staining characteristics each day of patient testing. 4. The technical supervisor confirmed that the laboratory performed a visual check on the stain acceptability each day of patient testing, but did not have a system in place at the time of the survey to document the acceptability of the stain indicated above. The number of patients tested with this stain could not be determined at the time of the survey.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assessment (QA) policies and procedures, review of Quality Control (QC) records and interview with the facility personnel, the laboratory failed to establish QA procedures to monitor QC results over time. Findings include: 1. The laboratory performs patient testing on the Vidas chemistry analyzer, with an approximate annual test volume of 612. 2. No QA documentation was presented for review during the survey to indicate the laboratory had a system in place to monitor QC results over time to detect shifts and trends in the QC data for testing performed on the Vidas analyzer. 3. The facility personnel confirmed that the laboratory failed to have a system in place at the time of the survey to detect shifts and trends in the control results.

**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:

The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6015 - ensuring that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved

proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing of the regulated analyte, serum hCG, under the sub-specialty of Endocrinology. See D2000 for findings.