

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2268159	<b>(X3) Date Survey Completed</b>  05/18/2023
<b>Name of Provider or Supplier</b>  Origin Fertility, Pa	<b>Street Address, City, State</b>  1643 Lancaster Dr Suite 309, Grapevine, TX	
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>D0000</b>	<p>An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5411</b>	<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: Based on review of manufacturer's instructions, quality control (QC) logs (May 2023), patient final reports and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing two levels of QC prior to patient testing for 9 of 9 days in May 2023. Findings Included: 1. Review of manufacturer's instructions for the "Bioscreen QC-Beads: Controls in Counting Sperm Using Manual and Automated Methods" (Revision 2/20) revealed the following: "In accordance with</p>

CLIA regulations, QC-Beads are supplied as two different levels of control. Procedure for Manual Counting of QC Beads: Count the beads using a standard counting procedure for counting sperm. 1. Invert the bottle several times to resuspend the Hi QC Beads. ...11. Repeat steps 1-10 using the Lo QC Beads." 2. Review of laboratory quality control logs for May 2023, revealed the following 9 of 9 days two levels of control were not performed prior to patient testing: a. 05/01/2023 QC Count High: No documentation b. 05/05/2023 QC Count Low: No documentation c. 05/08/2023 QC Count High: No documentation d. 05/11/2023 QC Count Low: No documentation e. 05/12/2023 QC Count High: No documentation f. 05/15/2023 QC Count Low: No documentation g. 05/16/2023 QC Count High: No documentation h. 05/17/2023 QC Count Low: No documentation i. 05/18/2023 QC Count High: No documentation 3. Review of patient final reports revealed the following 7 patients tested when two levels of quality control were not performed by the laboratory prior to patient testing: a. 05/01/2023 Accession: 002544 b. 05/05/2023 Accession: 002575 c. 05/08/2023 Accession: 002608 d. 05/11/2023 Accession: 002674 e. 05/15/2023 Accession: 002740 f. 05/17/2023 Accession: 002807 g. 05/17/2023 Accession: 002806 4. During an interview on 05/23/2023, at 11:25 a.m., in the conference room with Testing Person 2 (TP-2), TP-2 confirmed the QC-Beads were "rotated" between high and low each time of patient testing. This confirmed the laboratory failed to follow manufacturer's instructions for performing two levels of QC prior to patient testing for 9 of 9 days in May 2023.

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 review of laboratory policy, quality control (QC) logs (May 2023), patient final reports and confirmed in interview, the laboratory failed to document quality control sperm manual counts in duplicate for 9 of 9 days in May 2023. Findings Included: 1. Review of laboratory policies and procedures revealed the laboratory failed to have a quality control policy for manual sperm counts. 2. Review of laboratory sperm manual count quality control logs revealed the following 9 of 9 days the laboratory failed to document QC in duplicate prior to patient testing in May 2023: 05/01/2023; 05/05/2023; 05/08/2023; 05/11/2023; 05/12/2023; 05/15/2023; 05/16/2023; 05/17/2023; 05/18/2023 3. Review of patient final reports revealed the following patients tested when quality control was not documented in duplicate in May 2023: a. 05/01/2023 Accession: 002544 b. 05/05/2023 Accession: 002575 c. 05/08/2023 Accession: 002608 d. 05/11/2023 Accession: 002674 e. 05/15/2023 Accession: 002740 f. 05/17/2023 Accession: 002807 g. 05/17/2023 Accession: 002806 4. During an interview on 05/23/2023, at 11:30 a.m., in the conference room with Testing Person 2 (TP-2), TP-2 confirmed the QC was not documented in duplicate for 9 of 9 days in May 2023 prior to patient testing. This confirmed the above findings.

**D5543**

**HEMATOLOGY**  
CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control

material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instruction, quality control (QC) logs (May 2023), patient final reports and confirmed in interview, the laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 1 of 7 patients in May 2023.

Findings Included: 1. During a tour of the facility on 05/18/2023 at 12:05 p.m., the inspector observed 1 box of Microcell Counting Chamber slides used for manual sperm counts in the laboratory. 2. Review of manufacturer's instructions for the "Bioscreen QC-Beads: Controls in Counting Sperm Using Manual and Automated Methods" (Revision 2/20) revealed the following: "Procedure for Manual Counting of QC Beads: ..10. The average count should be within the range of the expected values. If the results are not within this range, then repeat steps 1-9. Expected Values: Counting chamber of 20 m thick, such as a Cell-Vu, Microcell or Standard Count: Lo QC Beads: between 15-21 million beads/ml." 3. Review of laboratory sperm count QC logs revealed the following: "QC Low Count: 16-24 million/ml" The laboratory failed to record the correct QC range for Lo QC Beads, using the Microcell Counting Chamber slides, on the sperm count QC log. Further review of the sperm count QC log revealed the following day QC was not within the manufacturer's expected value range: 05/08/2023 QC Low Count: 23 million/ml (Correct Range: 15-21 million beads /ml) 4. Review of patient final reports revealed the following patient tested and reported on the day of failed quality control: 05/08/2023 Accession: 002608 5. During an interview on 05/18/2023 at 12:10 p.m., in the conference room, TP-2 confirmed QC was not within range prior to patient testing for 1 of 7 patients reviewed in May 2023. This confirmed the above findings.