

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2164765	(X3) Date Survey Completed 10/09/2019
Name of Provider or Supplier Vios Fertility Institute - Hoffman Estates	Street Address, City, State 1585 Barrington Rd -, Hoffman Estates, IL	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with a representative for Vios Fertility Institute, the laboratory failed to have a comprehensive procedures manual that includes instruction for preanalytic, analytic, and postanalytic phases of testing. Findings: 1. The procedures did not include the following: a. Requirements for patient referral. b. Step-by-step performance of the procedure, including test calculations and interpretation of results. There were no procedures for documenting patients' tests performed in duplicate using a hemocytometer. c. Control procedures. There were no procedures for documenting</p>

control procedures performed in duplicate using a hemocytometer. d. The laboratory's system for entering results in the patient record and reporting patient results. e. Description of the course of action to take if a test system becomes inoperable. 2. At 11:00 AM on October 9, 2019, the representative for Vios Fertility Institute confirmed the surveyor's 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 review of the laboratory's procedures manual; patient's test records; and quality control (QC) records, and interview with a representative for Vios Fertility Institute, the laboratory failed to perform and document patient specimens and control materials in duplicate when it performed sperm counts using the hemocytometer. Findings: 1. The laboratory procedures instruct testing personnel to perform all procedures in duplicate. 2. Review of 4 patients test records revealed that there was no documentation to show patients' specimens were tested in duplicate when it performed sperm counts, using a hemocytometer, for 4 of 4 test records reviewed. 3. Review of corresponding QC records for 4 patients' tests revealed that there was no documentation to show control material were tested in duplicate for 4 of 4 days when patients' specimens were tested. 4. At 11:AM on October 9, 2019, the representative for Vios Fertility Institute confirmed the surveyor's findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures manual and patient test records and interview with testing personnel and a representative for Vios Fertility Institute, the test report did not include the name and address of the laboratory location where the test was performed. Findings: 1. Review of the laboratory's procedures manual revealed that the laboratory performed, only, sperm counts using a hemocytometer. 2. There were no procedures that described what information is included on the final report of patient testing. 3. Review of 4 patients' Electronic Medical Records (EMR) revealed that morphology results were reported for 4 of 4 patients' test records reviewed. 4. Testing personnel confirmed that she does not perform morphology on patients' specimens. 5. The representative for Vios Fertility Institute told the surveyor

that morphology is performed and reported at one of their other locations that performs high complexity testing. 6. At 11:00 AM on October 9, 2019, the representative for Vios Fertility Institute confirmed the surveyor's findings.