

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2131167	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier Ivf Virginia Llc	Street Address, City, State 700 Oak Grove Road, Chesapeake, VA	
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
D0000	An announced CLIA recertification survey was conducted at Procreate Fertility Center of Virginia on March 27, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of semen analysis proficiency testing (PT) documentation, and an interview, the laboratory failed to retain documentation of the Sperm Count Quality (SCQ) Analyzer instrumentation printed results for two (2) of three (3) events reviewed. Findings include: 1. Review of the laboratory's 2017 and 2018 College of American Pathologists (CAP) Semen Analysis PT documentation, a total of 3 events, revealed no SCQ instrument result print outs were retained for: 2018 Event 1, 2018 Event 2. The inspector requested to review the analyzer result print outs for the semen analysis events listed above. No documentation was available for review. 2. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.</p>

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

A. Based on a review of mycology proficiency testing (PT) records, and an interview, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) Wet Prep twice annually in calendar year 2018. Findings include: 1. Review of the laboratory's 2018 College of American Pathologists (CAP) Microscopy PT documentation, a total of two (2) events, revealed the laboratory utilized PT to verify KOH Wet Prep accuracy twice annually. A review of the CAP PT reports revealed the laboratory failed twice annual accuracy verification in 2018 by receiving the following unacceptable scores: 2018 1st Event Microscopy: 50% score- failed for CM-26 KOH. 2. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed. B. Based on a review of semen analysis (PT) records, and an interview, the laboratory failed to verify the accuracy of Sperm Count testing twice annually in calendar years 2017 and 2018. Findings include: 1. Review of the laboratory's 2017 and 2018 College of American Pathologists (CAP) Semen Analysis PT documentation, a total of three (3) events, revealed the laboratory utilized PT to verify Sperm Count accuracy twice annually. A review of the CAP PT reports revealed the laboratory failed twice annual accuracy verification by receiving the following unacceptable scores: 2017 2nd Event Semen Analysis: 0% Score- failed for SEM-19 and SEM- 20; 2018 2nd Event Semen Analysis: 50% Score- failed for SEM-20. 2. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on a tour, review of procedures, maintenance logs, manufacturer's package insert, Operations Manual, patient test logs, calibration records, and interviews, the laboratory failed to: 1. monitor and document laboratory relative humidity percent (%) to ensure the stability and storage requirements of Quick Check Semen pH and Leukocyte (WBC) reagent strips for seventeen (17) of 17 months reviewed (Cross Reference D5413); 2. use their McKesson Consult Diagnostics Human Chorionic Gonadotropin (hCG) Urine Test Dipstick test kit in a manner that was approved by the manufacturer, which is considered off-label use, from March 1, 2018 to March 27, 2019 (Cross Reference D5423); 3. document required weekly preventative maintenance on the Sperm Count Quality (SCQ) instrument for sixty-eight (68) of 68

weeks reviewed, while reporting five hundred sixty-two (562) patient semen analysis (Cross Reference D5429); 4. document calibration procedures for the SCQ analyzer every six (6) months in calendar year 2018 (Cross Reference D5437).

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a tour, review of procedures, maintenance logs, and an interview, the laboratory did not monitor and document laboratory relative humidity percent (%) to ensure the stability and storage requirements of Quick Check Semen pH and Leukocyte (WBC) reagent strips for seventeen (17) of 17 months reviewed. Findings include: 1. During a laboratory tour at approximately 12:00 PM, the inspector noted two (2) bottles of MES Quick Check Semen pH and WBC reagent strips (lot number 77962) stored in the semen analysis test lab. 2. Review of the procedure manual revealed a MES Quick Check manufacturer's package insert which included storage and stability guidelines that stated: "Store product test strips at 15 degrees Celsius (C) to 30 C. After bottle opening, store at the specified temperature and humidity less than 30% (very important)." 3. Review of the maintenance logs from 10/1/17 to 3/27/19, revealed recorded daily room temperatures but no recorded humidity levels for the semen analysis test lab. The inspector requested to review humidity records for the semen analysis test lab. No documentation of humidity monitoring was available. 4. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a tour, review of manufacturer's package insert, patient test logs, and interviews, the laboratory utilized McKesson Consult Diagnostics Human Chorionic Gonadotropin (hCG) Urine Dipstick test kits for analyzing patient serum samples that

was not approved by the manufacturer, which is considered off-label use, from March 1, 2018 to March 27, 2019. Findings include: 1. During a tour of the nursing test area, at approximately 12:00 PM, the inspector noted one (1) box of McKesson Consult Diagnostics hCG Urine Dipstick test kit (lot number HCG8090036) open for use and three (3) patient serum samples in a tube rack. During the tour, the primary testing personnel and primary nursing staff provided statements regarding the procedure of the utilized test kit: "We draw blood and use the serum for testing patients in their IVF cycle as we have not been satisfied with our reference lab results. All other appointment times, we use patient urine samples for the pregnancy testing." 2. Review of the Consult Diagnostics hCG Urine Dipstick package insert revealed that there were no instructions for performing the hCG test from a serum sample. The intended use statement was: "The McKesson Consult Diagnostics hCG Dipstick is a rapid immunoassay for the qualitative detection of hCG in urine to aid in the early detection of pregnancy". 3. A telephone conference call to a McKesson Technical Support specialist at approximately 2:00 PM, revealed that the Consult Diagnostics hCG test kit was not approved for testing patient serum samples and that such use would be considered off-label use of the test reagent kit. 4. Review of patient test logs, revealed one hundred twenty (120) hCG test results were reported using the method of serum sample testing described above (review period 3/1/18 to 3/27/19). 5. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.

D5429

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

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of instrument maintenance logs, manufacturer's operations manual, patient test logs, and an interview, the laboratory failed to document required weekly preventative maintenance for sixty-eight (68) of 68 weeks reviewed, while reporting five hundred sixty-two (562) patient semen analysis panels. Findings include: 1. Review of the laboratory's Sperm Count Quality (SCQ) Analyzer maintenance logs and manufacturer's MES SCQ Operations Manual revealed the following required preventative maintenance procedures listed as "perform weekly": Clean lower chamber with 'Blue Dot' cleaning capillary, Clean optical chamber with "Spongy" drying capillary. Review of the laboratory's SCQ instrument maintenance logs from 10/1/17 to 3/27/19 revealed that the laboratory failed to document performance of the weekly maintenance listed above for the 68 of 68 weeks reviewed. 2. Review of the laboratory's patient test logs revealed 562 semen analysis panels were resulted while documentation of the required preventative maintenance was not recorded. 3. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or

specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of procedures, calibration records, and an interview, the laboratory failed to document calibration procedures for the Sperm Count Quality (SCQ) Analyzer according to the frequency recommended by the manufacturer in calendar year 2018. Findings include: 1. Review of the SCQ Procedure Manual revealed a manufacturer's recommendation to calibrate at a frequency of every six (6) months. The manual stated "twice per year, perform SQA-V Gold calibration confirmation. Send the SQA-V calibration parameters for calibration confirmation and retain the subsequent comparison report". 2. Review of the laboratory's 2018 SCQ analyzer calibration records revealed one (1) calibration dated 11/28/18. The lab inspector requested to review additional calibration records for 2018. No additional documentation was available. 3. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to perform annual Sperm Count Quality (SCQ) Analyzer competency evaluations for two (2) of three (3) testing personnel in 2018. Findings include: 1. Review of the CMS Form 209: Laboratory Personnel Report revealed that the laboratory director also performs the duties of TC and that there are 3 testing personnel (TP). 2. Review of the laboratory personnel files revealed that TP A and TP B lacked a 2018 annual SCQ semen analysis competency evaluation. (See Personnel Code Sheet.) 3. In an exit interview with the primary TP at approximately 3:30 PM the above findings were confirmed.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on a tour, review of manufacturer's package insert, patient test logs, and interviews, the laboratory director (LD) did not ensure that the testing personnel (TP)

utilized the McKesson Consult Diagnostics Human Chorionic Gonadotropin (hCG) Urine Dipstick test kit in a manner that was approved by the manufacturer from March 1, 2018 to March 27, 2019. Findings include: 1. During a tour of the nursing test area, at approximately 12:00 PM, the inspector noted one (1) box of McKesson Consult Diagnostics hCG Urine Dipstick test kit (lot number HCG8090036) open for use and three (3) patient serum samples in a tube rack. During the tour, the primary testing personnel and primary nursing staff provided statements regarding the procedure of the utilized test kit: "We draw blood and use the serum for testing patients in their IVF cycle as we have not been satisfied with our reference lab results. All other appointment times, we use patient urine samples for the pregnancy testing." 2. Review of the Consult Diagnostics hCG Urine Test Dipstick package insert revealed that there were no instructions for performing the hCG test from a serum sample. The intended use statement was: "The McKesson Consult Diagnostics hCG Dipstick is a rapid immunoassay for the qualitative detection of hCG in urine to aid in the early detection of pregnancy". 3. A telephone conference call to McKesson Technical Support at approximately 2:00 PM, revealed that the Consult Diagnostics hCG test kit was not approved for testing patient serum samples and that such use would be considered off-label use of the test reagent kit. 4. Review of patient test logs, revealed one hundred twenty (120) hCG test results reported using the method of serum sample testing described above (review period 3/1/18 to 3/27/19). 5. In an exit interview with the primary testing personnel at approximately 3:30 PM the above findings were confirmed.