

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2180158	(X3) Date Survey Completed 06/04/2024
Name of Provider or Supplier Inovi Fertility & Genetics Institute	Street Address, City, State 3773 Richmond Ave, Suite 400, Houston, TX	
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 survey of the laboratory was conducted on 06/04/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, instructions to patients and staff interview, the laboratory failed to have protocols in place for specimen preservation /stability (interval/storage temperature), transport and acceptability/rejection criteria for one of one test performed by the laboratory, Semen Analysis. Findings included: 1. Review of laboratory's policies/procedures revealed the laboratory's Andrology procedures (effective date 11/1/2023) had the following instructions for Specimen: "A fresh semen sample collected by masturbation after 48-72 hours of abstinence (or the time period specified by physician) is required." The procedures did not have in place written protocols for specimen stability (interval/storage temperature), transport and rejection criteria for semen specimens tested in the laboratory. 3. Review of laboratory's instructions to patients revealed there were no written instructions for patients collecting samples outside the facility in regard to specimen preservation, transport and acceptability/rejection criteria. 3. In an interview on 06/04/2024 at 0930 hours in the breakroom, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, instruments' maintenance records and staff interview, the laboratory failed to follow its own policy and document maintenance for one of one microscope in use, the Olympus BX microscope. Findings included: 1. Review of laboratory's policy "Andrology: Microscope operation and Maintenance" (effective 11/01/2023) revealed: "After use for the day, the stage should be wiped clean, and the light source turned off." 2. Review of laboratory's instruments' maintenance records revealed there was no documentation of microscope cleaning or turning off as per the above policy. 3. In an interview on 06/04/2024 at 1135 hours in the breakroom, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.

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 review of manufacturer instructions, surveyor's observations and staff interview the laboratory failed to follow manufacturer instructions for reagent stability for 1 of 1 opened vial of Vitrolife Enhance SpermFreeze solution in use observed in the refrigerator. Findings included: 1. Review of manufacturer instructions for the Vitrolife Enhance SpermFreeze Solution (document 21115.06 SpermFreeze Solution (Trademark) Vitrolife) revealed: "Media bottles can be used for up to two weeks after first opening..." 2. Surveyor's observations on 06/04/2024 at 1100 hours in the laboratory revealed one opened vial of Vitrolife Enhance SpermFreeze solution stored in the refrigerator. The vial had a handwritten open date of 03/02/2024. 3. In an interview on 06/04/2024 at 1110 hours in the breakroom, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings. B. Based on surveyor's observations, review of manufacturer's instructions, laboratory's temperature records and staff interview, the laboratory failed to follow manufacturer instructions for storage temperature for 3 of 3 andrology supplies stored in the refrigerator. Findings included: 1. Surveyor's observations on 06/04/2024 at 1100 hours in the laboratory revealed the following supplies stored in the refrigerator: a. ORIGIO Gradient 40/80: Lot 23721-016548, expiration date 2024-07-19 b. Fujifilm Sperm Washing Medium: Lot 0000021239, expiration date 2025-01-31 c. Vitrolife Enhance SpermFreeze: Lot CT23SF26, expiration date 2025 2. Review of

manufacturer instructions for storage for the above supplies revealed the following storage temperature requirements: a. ORIGIO Gradient 40/80 - storage temperature 2-8C (Degrees Celsius). b. Fujifilm Sperm Washing Medium - storage temperature 2-8C. c. Vitrolife Enhance SpermFreeze - storage temperature 2-8C. 3. Review of laboratory's random temperature records revealed the laboratory defined acceptable refrigerator temperature range as 1-10C. 4. Further review of temperature records for May and April 2024 revealed the following days refrigerator temperature was out of manufacturer requirements for storage of the above supplies: Date: Maximum Temperature (C): 04/01/2024 8.1 04/02/2024 8.1 04/03/2024 8.1 04/04/2024 8.1 04/05/2024 8.1 04/08/2024 8.1 04/09/2024 8.1 04/10/2024 8.1 04/11/2024 8.1 04/15/2024 8.1 04/16/2024 8.1 04/17/2024 8.1 04/18/2024 8.1 04/19/2024 8.1 04/20/2024 8.1 04/22/2024 8.1 04/23/2024 8.1 04/24/2024 8.1 04/25/2024 8.1 04/29/2024 8.1 04/30/2024 8.1 05/01/2024 8.1 05/02/2024 8.1 05/03/2024 8.1 05/01/2024 8.1 05/02/2024 8.1 05/07/2024 8.1 05/13/2024 8.1 05/14/2024 8.1 05/15/2024 8.1 05/16/2024 8.1 05/17/2024 8.1 05/18/2024 8.1 05/20/2024 8.1 05/21/2024 8.1 05/22/2024 8.1 05/23/2024 8.1 5. In an interview on 06/04/2024 at 1110 hours in the breakroom, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.

D5415

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

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

This STANDARD is not met as evidenced by:
 Based on surveyor's observations, review of laboratory's policies/procedures and staff interview, the laboratory failed to label 3 of 3 in use Quik-Dip Stain reagents' coplin jars with preparation date, expiration date and lot number. Findings included: 1. Surveyor's observations on 06/04/2024 at 1030 hours in the laboratory revealed 3 Quik-Dip Stain reagents' coplin jars sitting by the sink in the laboratory. The coplin jars were labeled as "Morph (morphology) Stain Sol. (solution) A 1/18/24", "Morph Stain Sol. B 1/18/24" , and "Morph Stain Sol. C 1/18/24". These containers were not labeled with the preparation date, expiration date or lot number. 2. In an interview on 06/04/2024 at 1030 hours in the laboratory, the Testing Person number 2 (as indicated on submitted form CMS 209) stated the coplin jars contained the Quik-Dip Stain solutions and the 1/18/24 date on the jars was the open date of the original container of the solution in the jar, not the date the solution was poured into the container, or the expiration date. 3. Review of laboratory's policies/procedures revealed there were no protocols in place delineating secondary container labeling requirements. 4. In an interview on 06/04/2024 at 1035 hours in the laboratory, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.

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 review of laboratory's policies/procedures, quality control (QC) records and staff interview, the laboratory failed to document QC for reactivity of 1 of 1 stain used for staining semen specimen slides for determination of sperm morphology, and content of white blood cells (WBC), the Quik-Dip Stain. Findings included: 1. Review of laboratory's policy "Differential Stain for WBCs" (effective 11-01-2023) revealed: "Perform Quality Control for Testsimplets each day of use. A semen sample with WBCs (neutrophils) present and identifiable is sufficient for documentation. If no suitable semen sample is available, a 5 ul drop of blood from a fresh sample collected in an EDTA tube is satisfactory." 2. Review of laboratory's policy "Morphology Assessment" (effective 11-01-2023) revealed: "QUALITY CONTROL: ... This evaluation should be performed each day slides are stained (sic) and documentation maintained on the SA QC record." 3. Review of laboratory's QC records for 2023 and 2024 revealed there was no documentation of QC for the Quik-Dip Stain used for staining semen specimen slides for determination of sperm morphology, and content of WBC. 4. In an interview on 06/04/2024 at 0950 hours in the breakroom, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.