

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2176542	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Family Fertility Center - Ivf	Street Address, City, State 17350 St Luke'S Way, Suite 300, The Woodlands, 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	<p>An announced survey of the laboratory was conducted on 09/07/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, 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 CMS Southern Operations Branch-Dallas for referral to the Office of 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>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted form CMS 209, personnel records, policies /procedures and staff interview, the laboratory failed to document competency assessment for one of one general supervisor employed by the facility. Findings included: 1. Review of laboratory's submitted form CMS 209 (Laboratory Personnel Report) revealed the laboratory employed one General Supervisor. 2. Review of personnel records for the laboratory's General Supervisor revealed there was no competency assessment documented for the individual holding this position. 3. Review of laboratory's policies/procedures revealed there was no protocol in place to</p>

access General Supervisor's competency based on position's duties. The laboratory did not have delegation of duties for General Supervisor documented. 3. In an interview on 09/07/2023 at 1035 hours in the conference room, the laboratory's General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

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, random patient test records from 2022 and staff interview, the laboratory failed to follow its own policy for turnaround time (TAT) and abstinence requirements for 3 of 23 patients' test records reviewed. Findings included: 1. Review of the laboratory's policy/procedure "Fresh Semen Sample Collection" (last updated July 1, 2023) revealed: "V. FRESH SEMEN SAMPLE COLLECTION ... Ideally, the time of analysis or processing should be no later than one-hour post-collection." And, "VI. CRITERIA FOR REJECTION ... D. Semen samples for Semen Analysis will also be rejected if the abstinence period is not within the recommended 2-7 days window." 2. Review of random patient test records from 2022 revealed: a. The following patient's sample did not follow the laboratory's TAT requirements for semen analysis: Sample Accession #: C-213 Collection date: 03/09/2022 Collection time: 08:27 Time of analysis: 09:45 Time elapsed from collection to start of analysis: 1 hour 18 minutes Note: The laboratory's policies did not address analysis TAT for other than ideal circumstances. The maximum time allowed from collection to analysis start without the requirement for rejection was not specified. b. The following patients' samples were collected outside the recommended abstinence interval: Sample Accession #: C-217 Collection date: 03/16/2022 Collection time: 07:45 Time of analysis: 08:10 Abstinence days: 1 Sample type: post-vasectomy Sample Accession #: C-264 Collection date: 10/27/2022 Collection time: 08:03 Time of analysis: 08:15 Abstinence days: 1 Sample type: post-vasectomy Note: The laboratory's policies did not address post-vasectomy sample testing requirements. 3. In an interview on 09/07/2023 at 1220 hours in the conference room, the laboratory's General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, test volumes and staff interview, the laboratory failed to establish protocols for ensuring quality control is maintained for sperm motility and progression for one of one tests performed by the facility, Semen Analysis. Findings included: 1. Review of the laboratory's policies/procedures revealed the laboratory did not have protocols in place to address quality control for interpretation of sperm motility and progression. 3. Review of laboratory's test volumes revealed the laboratory performed 127 semen analysis annually. 2. In an interview on 09/07/2023 at 1125 hours in the conference room, the laboratory's General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

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 quality control (QC) records, policies/procedures, patient test volumes and staff interview, the laboratory failed to document testing of staining materials for intended reactivity each day of use for one of one stain procedure, the Diff Quik Stain. Findings included: 1. Review of laboratory's QC records for May-August 2022 and April to July 2023 revealed the laboratory did not document the Diff Quick Stain reagents for intended reactivity each day of patient testing. 2. Review of laboratory's policies/procedures did not address verification of Diff Quick Stain reagents' intended reactivity. 3. Review of laboratory's patient test volumes revealed the laboratory performed approximately 127 semen analysis annually. 4. In an interview on 09/07/2023 at 1125 hours in the conference room, the laboratory's General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid