Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2176542	10/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Family Fertility Center - Ivf	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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and CMS Form 209 provided at the time of the survey, review of laboratory's policies, and staff interview it was determined the laboratory failed to establish and follow policies for performing competency assessment for 1 of 1 Clinical Consultant. The findings were: 1. Review of the laboratory's personnel records and CMS Form 209 provided at the time of the survey revealed the laboratory employed one Clinical Consultant. 2. Review of the laboratory's policies revealed there was no policy addressing competency assessment for the laboratory's Clinical Consultant. 3. Review of the laboratory's personnel

	records revealed no documentation of competency assessment for the Clinical Consultant. 4. In an interview on 10/13/2021 at 1100 hours in the conference room the Laboratory Director (as described on CMS Form 209 signed by laboratory director on 10/13/2021) confirmed the findings
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: Based on review of the laboratory's test menu and CMS Form 116 provided at the time of the survey, review of the laboratory's records for 2020 and staff interview it was determined the laboratory failed to document twice annual accuracy assessment for one of one tests performed within the laboratory in 2020. The findings were: 1. Review of the laboratory's CMS Form 116 provided at the time of the survey and its test menu revealed the laboratory performed the following tests: Complete Semen Analysis 2. Review of the laboratory's records for 2020 revealed there was no documentation of twice annual accuracy assessment for Complete Semen Analysis in 2020. 3. In an interview on 10/13/2021 at 1130 hours in the conference room the Laboratory Director (as described on CMS Form 209 signed by laboratory director on 10/13/2021) confirmed the findings.
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 a review of the laboratory's policies, the Diff-Quik Staining Kit log sheets, patient test records, and staff interview, it was revealed the laboratory failed to follow its own procedure by not performing the Diff-Quik stain QC (quality control) for 12 of 20 months from February 2020 to October 2021. Findings include: 1. A review of the laboratory's policy titled 'Semen Analysis' revealed the following: "Morphology Assessment (Diff-Quik stain) Stain QC Three blank slides should be prepared to check that the fixative and stains do not have any sperm contamination. Slide one should be the fixative only. Slide two should be stained with Stain A. Slide three should be stained with Stain B. Slides should then be air dried and checked for potential contamination." 2. A review of the Diff-Quik Staining Kit log sheet revealed the laboratory performed the Stain QC monthly. 3. Further review of the Diff-Quik Staining Kit log sheet revealed the laboratory failed to have documentation of performing the Diff-Quik Stain QC for the 12 months from November 2020 to October 2021. 4. A review of patient test records revealed the following 4 patient specimens were processed using the Diff-Quik stain when there was no documentation that the laboratory performed the monthly Stain QC, ensuring the stain was not contaminated: Patient: 8109177 Tested: 11/13/20 Patient: 3002964509 Tested: 3/12/21 Patient: 3000134748 Tested: 4/14/21 Patient: 3003039746 Tested: 7/9

	/21 5. An interview with the laboratory director on 10/13/21 at 12:30 p.m. in the conference room, after review of the records, confirmed the above 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 surveyor observation, a review of the operations manual for the Olympus BX43 System Microscope, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of monitoring the humidity of the laboratory where the Olympus BX43 microscope was stored for 20 of 20 months from February 2020 to October 2021. Findings include: 1. During a tour of the facility on 10/13/21 at 10:30 a.m. the following laboratory equipment was found in the laboratory: - Olympus BX43 System Microscope 2. A review of the operations manual for the laboratory equipment stored in the laboratory revealed the manufacturer required the following conditions for operation: Olympus BX43 System Microscope (M 0200, April 2019) "Ambient temperature: 5C to 40C (41 to 104 F) Maximum relative humidity: 80% for temperatures up to 31C (88F) , decreasing linearly through 70% at 34C (93F), to 60% at 37C (99F), to 50% relative humidity at 40C (104F)." 3. A review of the laboratory's records revealed the laboratory started testing in February 2020. The laboratory failed to have documentation of monitoring the humidity of the laboratory where the Olympus BX43 microscope was stored for 20 of 20 months from February 2020 to October 2021. 4. An interview with the laboratory director on 10/13/21 at 11:10 a.m. in the conference room, after review of the records, confirmed the above findings. Key: C = Degrees Celsius F = Degrees Fahrenheit
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory's policies, review of the laboratory's personnel records and staff interview it was determined the technical supervisor failed to have documentation of assessing the competency, at least twice during the first year of patient testing, for two of three testing personnel in 2020. The findings were: 1. Review of the laboratory's policy Personnel Training Accessing Personnel Competency revealed: "II. For a new employee, competency assessment must be performed 6 months post initial assessment evaluation. III. For a new employee, competency assessment must be performed 1 year post initial assessment evaluation"

	2. Review of the policy Technical Supervisor Responsibilities revealed: "Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently." 3. Review of the laboratory's personnel records revealed only one competency assessment was performed within the first year of testing personnel employment as follows: Testing Person #2 - Hired February 2020 Competency assessment performed 04/15/2020 Testing Person #3- Hired February 2020 Competency assessment performed 04/15/2020 Note: The laboratory started testing on February 14, 2020. 4. In an interview on 10/13/2021 at 1100 hours in the conference room the Laboratory Director (as described on CMS Form 209 signed by laboratory director on 10/13/2021) confirmed the findings.