Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2202259	05/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Fertility Center - Medical City	7777 Forest Ln Suite D-1100, Dallas, 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 onsite routine recertification survey was performed on 05/17/2024 and the laboratory was found to not be in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1487 Laboratories performing high complexity testing; testing personnel
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 policy, review of proficiency testing (PT) records and confirmed in interview, the laboratory failed to verify the accuracy of sperm count for one of two testing events in 2023 (Event 2), sperm motility for one of two testing events in 2022 (Event 2), and one of two events in 2023 (Event 1). Findings include: 1. Review of the laboratory's policy titled "Policy for Proficiency Testing" determined: "If a proficiency test sample(s) receives and unacceptable score, the laboratory director will evaluate and document any corrective action taken." 2. Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing records determined: a) Embryology, Andrology & Fetal S2 2022: Method: Sperm Motility Score: 50 b) Embryology, Andrology & Fetal S1 2023: Method: Sperm Count, traditional Score: 50 Method: Sperm Motility Score: 50 3. The laboratory was asked to provide documentation of performing twice annual accuracy for non-regulated analytes that did not meet acceptable proficiency testing scores. No documentation was provided. 4. The Clinical Consultant confirmed the findings during an interview on 05/17/2023 at 1330 hours in the office.
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 the laboratory's policy, laboratory maintenance logs, and confirmed in interview, the laboratory failed to follow their own procedure for performing and documenting morphology stain replacement for nine of nine events in 2023 and three of three events in 2024. Findings include: 1. Review of the laboratory's policy titled "MORPHOLOGY STAINING" determined: "9. Procedure Notes d. To avoid stain contamination or inadequate staining resulting in false positive diagnosis of bacteriospermia or other inaccuracies, all three staining solutions should be examined for cloudiness, presence of foreign bodies, or other signs of improper staining daily and must be replaced every two weeks." 2. Review of the laboratory's maintenance log titled "Dallas Fertility Center - ANDROGLOGY Start-Up / Shutdown" determined morphology stain was replaced on the following days: 2023: Stain Changed: 01/18/2023 Stain Changed: 02/08/2023 (20 days elapsed) Stain Changed: 03/10/2023 (32 days elapsed) Stain Changed: 04/26/2023 (46 days elapsed) Stain Changed: 05/10/2023 (14 days elapsed) Stain Changed: 06/28/2023 (48 days elapsed) Stain Changed: 07/12/2023 (14 days elapsed) Stain Changed: 07/26/2023 (14 days elapsed) Stain Changed: 08/23/2023 (27 days elapsed) Stain Changed: 09/20 /2023 (27 days elapsed) Stain Changed: 10/06/2023 (16 days elapsed) Stain Changed: 10/20/2023 (14 days elapsed) Stain Changed: 12/13/2023 (53 days elapsed) 2024: Stain Changed: 01/19/2024 (36 days elapsed) Stain Changed: 02/28/2024 (39 days elapsed) Stain Changed: 03/13/2024 (15 days elapsed) The laboratory was asked to provide documentation of replacing morphology stain every two weeks as written in their laboratory policy. No documentation was provided. 3. The Clinical Consultant confirmed the findings during an interview on 05/17/2024 at 1325 hours in the office.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, quality control (QC) logs, patient final reports, and confirmed in interview, the laboratory failed to ensure two levels of sperm count quality control were within established acceptability, prior to reporting patient test results for 11 of 11 patient test results in 2023. Findings include: 1. Review of the laboratory's policy titled "SEMEN ANALYSIS QUALITY CONTROL" determined: "Quality Control: ...When counting each side of the counting chamber, for each control, the counts must be within 10% of each other. If this does not occur, then the affected control must be repeated." 2. Review of the manufacturer's instructions "accu-beads A Quality Control Check for Automated and Manual Sperm Counting Methods" version 2021-09-20 determined: "Manual Counting Procedures ...The results should be within 10% of each other to be considered valid." 3. Review of the laboratory's QC logs determined quality control

	values were out of range for the following days: 01/10/2024: QC Level: 2 Value 1: 16 Value 2: 20 Difference: 22.2% 01/19/2024: QC Level: 1 Value 1: 32 Value 2: 39 Difference: 19.7% QC Level: 2 Value 1: 17 Value 2: 20 Difference: 16.2% 02/07 /2024: QC Level: 1 Value 1: 31 Value 2: 38 Difference: 20.3% 02/16/2024: QC Level: 1 Value 1: 31 Value 2: 37 Difference: 17.6% QC Level: 2 Value 1: 16 Value 2: 20 Difference: 22.2% 4. Further review of patient reports determined testing was performed on days in which QC was outside acceptable limits. The patients were: 01 /10/2024: a) Patient ID: 57437 b) Patient ID: 52335 c) Patient ID: 47410 d) Patient ID: 66653 e) Patient ID: 66878 01/19/2024: a) Patient ID: 60038 b) Patient ID: 63772 c) Patient ID: 60868 02/07/2024: a) Patient ID: 67440 b) Patient ID: 65483 02/16 /2024: a) Patient ID: 67041 5. The Clinical Consultant confirmed the findings during an interview on 05/17/2024 at 1325 hours in the office.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records and staff interview, the laboratory failed to ensure one of four testing persons (TP-2) met the requirements to perform high complexity testing. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

	program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of four testing persons (TP-2) met the requirements to perform high complexity testing. Findings included: 1. Review of laboratory policy titled "HIGH COMPLEXITY LABORATORY PERSONNEL REQUIREMENTS" determined: "E. Testing Personnel 1. The laboratory must have a sufficient number of individuals who meet the Qualifications to perform high complexity testing." 2. Review of the CMS-209 form listed TP-2 as performing high complexity testing. 3. Review of personnel records for TP-2 included collegiate transcripts. The educational documents did not meet the qualifications for serving as a high complexity testing person. 4. The Clinical Consultant confirmed the findings during an interview on 05/17/2024 at 1325 hours in the office.