Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2202259	06/23/2026
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 routine recertification survey of the laboratory was completed on 06/23/2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 ten of ten events in 2025 and three of three events in 2026. Findings include: 1. Review of the laboratory's policy titled "ANDRO-SOP-04 Morphology Staining" stated: "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 "Medical City ANDROLOGY Start-Up / Shutdown" determined morphology stain was replaced on the following days: 2025: Stain Changed: 01/30/2025 Stain Changed: 02/20/2025 (21 days elapsed) Stain Changed: 03/27/2025 (35 days elapsed) Stain Changed: 04/24/2025 (28 days elapsed) Stain Changed: 05/27/2025 (33 days elapsed) Stain Changed: 06/03/2025 (7 days elapsed) Stain Changed: 07/29/2025 (56 days elapsed) Stain Changed: 07/31/2025 (2 days elapsed) Stain Changed: 08/07/2025 (7 days elapsed) Stain Changed: 09/02/2025 (26

	days elapsed) 2026: Stain Changed: 01/22/2026 (142 days elapsed) Stain Changed: 02 /26/2026 (35 days elapsed) Stain Changed: 04/28/2026 (61 days elapsed) 3. The Clinical Consultant (as listed on the CMS-209 form) confirmed the findings during an interview on 06/23/2026 at 1310 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers 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 12 of 12 patient test results in 2026. Findings include: 1. Review of the laboratory's policy titled "ANDRO-SOP-14 Semen Analysis Quality Control (Accu-beads)" stated: "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" stated: "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: a. 01/22/2026: QC Level: Low Value 1: 17 Value 2: 20 Difference: 16.2% b. 02/03/2026 QC Level: Low Value 1: 16 Value 2: 20 Difference: 22.2% c. 02 /26/2026: QC Level: Low Value 1: 16 Value 2: 18 Difference: 11.8% d. 03/17/2026: QC Level: Low Value 1: 18 Value 2: 15 Difference: 18.2% e. 03/19/2026 QC Level: Low Value 1: 17 Value 2: 15 Difference: 12.5% f. 03/24/2026 QC Level: Low Value 1: 16 Value 2: 18 Difference: 11.8% g. 04/16/2026 QC Level: Low Value 1: 15 Value 2: 19 Difference: 23.5% h. 04/28/2026 QC Level: Low Value 1: 15 Value 2: 18 Difference: 18.2% i. 05/05/2026 QC Level: Low Value 1: 18 Value 2: 16 Difference: 11.8% j. 05/07/2026 QC Level: Low 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: 01/22/2026: a) Accession #: 731654 b) Accession #: 731470 02/03/2026: a) Accession #: 734197 02/26/2026: a) Accession #: 738839 03/17/2026: a) Accession #: 744085 03/19/2026: a) Accession #: 745968 03/24/2026: a) Accession #: 734333 b) Accession #: 746891 04/16/2026: a) Accession #: 751161 04/28/2026: a) Accession #: 755620 05/05/2026: b) Accession #: 757536 05/07/2026: c) Accession #: 742995 5. The Clinical Consultant (as listed on the CMS-209 form) confirmed the findings during an interview on 06/23/2026 at 1148 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services