Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2202259	08/09/2022
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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director and testing personnel signing 6 of 6 attestation statements. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 (event 2) and 2022 (event 1) identified the following attestation statements were not signed by the laboratory director: a) 2021 Event 2 Sperm Morphology Sperm Count Sperm Motility b) 2022 Event 1 Sperm Morphology Sperm Count Sperm Motility 2. The laboratory was asked to provide documentation of the identified personnel signing the

	attestation statements. No documentation was provided. 3. An interview with the quality assurance manager on 08/09/2022 in Room 3 at 930 hours revealed the personnel would enter their names when the results were entered electronically, but did not sign the attestation as required. This confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' proficiency results from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of the review of results for 2 of 2 events. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2021 (event 2) and 2022 (event 1) identified the following results did not have documentation of review: a) 2021 Event 2 b) 2022 Event 1 2. The laboratory was asked to provide documentation of the review of the results. No documentation was provided. 3. An interview with the quality assurance manager on 08/09/2022 in Room 3 at 930 hours - after his review of the records - confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports, and staff interview, it was revealed the laboratory failed to identify the correct testing facility on 9 of 9 reports reviewed. The findings include: 1. A sampling of patient test reports from July 2021 to July 2022 identified 9 of 9 results which had the wrong analysis facility identified on the report. Analysis facility should have been identified as Medical City. They were: a) July 21, 2021 Accession: 395764 Analysis Facility: Dallas b) July 28, 2021 Accession: 396394 Analysis Facility: Dallas c) September 22, 2021 Accession: 407639 Analysis Facility: Dallas d) September 29, 2021 Accession: 408802 Analysis Facility: Dallas e) November 10, 2021 Accession: 416745 Analysis Facility: Dallas f) November 10, 2021 Accession: 415758 Analysis Facility: Dallas g) May 25, 2022 Accession: 450402 Analysis Facility: Dallas h) July 1, 2022 Accession: 458699 Analysis Facility: Dallas i) July 13, 2022 Accession: 458466 Analysis Facility: Dallas 2. An interview with the quality assurance manager on 08/09/2022 at 1115 hours in the laboratory - after his review of the records- confirmed the findings. He did not know why the wrong analysis facility was being identified on the patient report.

D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director approving 7 of 7 procedures currently in use. The findings include: 1. A review of the laboratory's procedure manual identified 7 of 7 procedures which did not have documentation of laboratory director approval. They were: 1. Semen Analysis 2. Morphology Staining 3. Viability Staining 4. Patient Specimen Identification 5. Patient and Procedure Identification and Specimen Accessioning 6. Laboratory Equipment 7. Semen Analysis Quality Control Each of the 7 procedures were approved by the quality manager. 2. The laboratory was asked to provide documentation of laboratory director approving the identified procedures. No documentation was provided. 3. An interview with the quality assurance manager on 08/09/2022 at 0945 hours in room 3 - after his review of the records- confirmed the findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing competency assessments on testing personnel. The findings include: 1. A review of the laboratory's personnel records identified 3 of 3 competency assessments which were documented as being performed by someone other than the technical supervisor. Testing personnel #1 semiannual 2021 annual 2022 Testing personnel #2 semiannual 2021 Each competency assessment was documented as being performed by the quality assurance manager. 2. The laboratory was asked to provide documentation of the technical supervisor performing the identified competency assessments. No documentation was provided. 3. An interview with the quality assurance manager on 08/09/2022 at 0930 hours in room 3 - after his review of the records- confirmed the findings.