Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2064554	02/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Fertility Center- Southlake	910 E Southlake Drive, Southlake, 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	Entrance and exit conferences were held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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 to be 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 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.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Proficiency Testing (PT) records from 2019 and confirmed in interview, the laboratory failed to retain result forms and attestation sheets for 1 of 2 testing events in 2019. Findings included: 1. Review of the CAP PT for 2019 revealed the laboratory did not retain the result forms and attestation sheets submitted to the PT company for the following event and samples tested: SPCD-A 2019: PT samples SPCD-01 and SPCD-02 (results reviewed and signed 06/17/2019) 2. During an interview on 02/03/2020 at 1100 hours, the Laboratory Director confirmed the above findings. The laboratory was unable to provide the result forms and attestation sheets for the above event.

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 random review of patient test reports for Semen Analysis (2018 and 2019) and in interview with staff, the laboratory failed to ensure the final test report included the CLIA number and/ or address of the laboratory location where the testing was performed for 7 of 7 reports. Findings included: 1. A random review of patient test reports for Semen Analysis revealed that testing for the following patients was performed at Dallas Fort Worth Fertility Associates, 910 East Southlake Boulevard, Suite 175, Southlake, Texas. The CLIA number for this location is 45D2064554. Further review of final patient test reports revealed the following for the CLIA number and/or address of the testing location: a. 06/15/2018; Patient 329-18 CLIA number on final report: 45D2010688 b. 11/15/2018; Patient 562-18 CLIA number on final report: 45D2010688 c. 11/08/2019; Patient 554-19 CLIA number on final report: 45D2010688 d. 11/22/2019; Patient 576-19 CLIA number on final report: 45D2010688 e. 11/27/2019; Patient 583-19 CLIA number on final report: 45D2010688 Address of testing location on final report: 5477 Glen Lakes Drive, Suite 201, Dallas, Texas f. 12/13/2019; Patient 594-19 CLIA number on final report: 45D2010688 g. 12/20/2019; Patient 604-19 CLIA number on final report: 45D2010688 Address of testing location on final report: 5477 Glen Lakes Drive, Suite 201, Dallas, Texas 2. In an interview on 02/03/2020 at 1100 hours in the office, the laboratory director confirmed that the final report did NOT include the CLIA number and/ or address of the laboratory location where the testing was performed. He stated that the CLIA number and Dallas, Texas address were another branch of the facility. This confirmed the findings. Word Key: CLIA = Clinical Laboratory Improvement Amendments