

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2064554	(X3) Date Survey Completed 05/26/2021
Name of Provider or Supplier Dallas Fertility Center- Southlake	Street Address, City, State 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	<p>An entrance conference was held with the laboratory representative. 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.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy College of American Pathologists (CAP) proficiency testing (PT) records, CAP codes instructions, and confirmed in staff interview, the laboratory failed to document a self-grade of Sperm analytes (unregulated) not evaluated or scored by the PT company for 1 of 2 events in 2020 (SPCD-B 2020). Findings: 1. Review of the laboratory policy titled "Proficiency Testing Policy" stated the following: "In the event that a score returned as "not graded" by the proficiency testing agency, the laboratory director will evaluate the</p>

reported values and document any corrective action taken." 2. Review of the CAP code instructions "Actions Laboratories Should Take when PT Result is Not Graded" revealed the following: Code: "26" Code description: "Educational Challenge" Action Required: "Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. Response to the CAP is not required." 2. Review of the CAP Sperm Morphology & Motility Online PT records for event SPCD-B 2020 revealed the laboratory failed to verify and document accuracy of results obtained for that event as follows: Method: Sperm motility WHO5 DISPOSABLE CNTNG CHMBR Specimen: SPCD-05; Result: 74 P; Grade: See Note [26] Specimen: SPCD-06; Result: 60 P; Grade: See Note [26] Method: Forward Progression WH DISPOSABLE CNTNG CHMBR Specimen: SPCD-05; Result: 74 P; Grade: See Note [26] Specimen: SPCD-06; Result: 60 P; Grade: See Note [26] Method: Non Progressive WHO5 DISPOSABLE CNTNG CHMBR Specimen: SPCD-05; Result: 26 P; Grade: See Note [26] Specimen: SPCD-06; Result: 40 P; Grade: See Note [26] Method: Sperm motility Non WHO DISPOSABLE CNTNG CHMBR Specimen: SPCD-05; Result: 3 P; Grade: See Note [26] Specimen: SPCD-06; Result: 3 P; Grade: See Note [26] Method: Sperm Viability [sic] Specimen: SM2CD-03; Result: 30 P; Grade: See Note [26] Specimen: SM2CD-04; Result: 13 P; Grade: See Note [26] Method: Sperm Viability [sic] - Digi Specimen: SM2CD-03D; Result: 30 P; Grade: See Note [26] Specimen: SM2CD-04D; Result: 13 P; Grade: See Note [26] Review of the CAP "Original Evaluation" form stated: "[26] = Educational challenge" "P = Based on peer group statistics" 3. During an interview on 05/26/2021 at 9:46 a. m., the Laboratory Director confirmed there was no documentation of review and verification of accuracy for the above-mentioned analytes.