

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2156076	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier Dallas Fertility Center-Perot	Street Address, City, State 8160 Walnut Hill Ln Suite 213, 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 survey of the laboratory was conducted on 11/07/2024. 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.
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, staff interview, review of laboratory's policies /procedures, quality control (QC) records and annual test volumes, the laboratory failed to document the lot number and open/expiration date of Accu-beeds controls (Vial 1 and Vial 2) used to assess QC for Sperm count testing for seven of seven random months reviewed in 2023 and 2024. Findings included: 1. Surveyor's observations on 11/07/2024 at 0910 hours in the laboratory revealed a box of Spectrum Technologies Accu-beeds, marked as received on 10/10/2023, containing: Vial 1 (18M [million]/ml [milliliter]); lot number 223011181, expiring December 2024 Vial 2 (35M/ml); lot number 230604351, expiring April 2025 2. In an interview on 11/07/2024 at 1130 hours in the facility's reception area the laboratory director stated that the laboratory performed QC for sperm count with two levels of Spectrum Technologies Accu-beeds. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place to ensure QC material's lot numbers and</p>

expiration dates were documented. 4. Review of random QC records revealed the following seven of seven months did not have documentation of the lot number or expiration date of the Sperm Count QC Accu-beeds control solutions: April 2023 November 2023 March 2024 April 2024 May 2024 June 2024 August 2024 5. Review of laboratory's annual test volumes revealed that the laboratory performed approximately 40 sperm analysis tests (with sperm counts) annually. 6. In an interview on 11/07/2024 at 1135 hours in the facility's reception area the laboratory director (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid