Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2156076	03/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Fertility Center-Perot	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 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 deficiency and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representative was 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 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.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions for Harleco Hemacolor Stain Set and interview with staff, the laboratory failed to follow the manufacturer's instructions for staining semen slide specimens. Findings Included: 1. Review of the laboratories procedure titled "Morphology Staining" (Effective and signed by the Laboratory Director on 2/25/2019), stated the following: "..Procedure .... 5. Fix the smear by immersing the slide for a minimum of 5 to 7 dips (10 seconds)

	in a Coplin Jar containing fixative. 6. Stain for 5 to 7 dips(10 seconds) in the red stain (Stain A). 7. Stain for 5 to 7 dips(10 seconds) in the blue stain(Stain B). 8. Rinse under running tap water ...." 2. Review of the manufacturer's instructions for the Harleco Hemacolor Stain Set stated the following: " Procedure ...3. Immerse slide five times for one second each time into Solution 1. Allow excess to slowly drip off. 4. Immerse slide for one second each time into Solution 2, remove and hold in air for one second. Repeat 3 times. 5. Immerse slide for one second in Solution 3, remove and hold in air for 1 second. Repeat 3 to 5 times. Allow the excess solution to drip off. 6. Rinse slide with ultrapure water ...." The laboratory failed to follow manufacturer's instructions for slide staining using Harleco Hemacolor stain set. 3. In an interview with the laboratory manager on 03/03/2021 at 10:55am in the office, the laboratory manager, after review of the findings, confirmed the laboratory failed to follow manufacturer's instructions.