

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2064554	(X3) Date Survey Completed 03/24/2023
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, patient requisitions, patient final reports, and confirmed in interview, the laboratory failed to ensure 5 of 10 patient requisitions from January 2023 through February 2023 (random review) solicited tests to be performed. Findings: 1. Review of the laboratory's policy "Patient and Procedure Identification and Specimen Accessioning" revealed: "Policy 1. Greet the patient professionally, have him check-in and fill out the appropriate paper work [sic]. Patient should have a signed and complete physician office originated laboratory requisition form with him, or a completed faxed requisition should be on file at the DFC reception desk. 2. Accepting a collected specimen or having the patient collect a</p>

specimen should be delayed until the appropriate paperwork, physician order and patient/ specimen identification can be confirmed." 2. A random review of patient requisitions from January 2023 through February 2023 revealed the following patient requisitions that failed to indicate the seamen analysis testing that was to be performed by the laboratory: Patient Accession #: 490653, requisition date: 01/18/2023 Patient Accession #: 495276, requisition date: 01/20/2023 Patient Accession #: 495024, requisition date: 01/20/2023 Patient Accession #: 496499, requisition date: 01/20/2023 Patient Accession #: 501743, requisition date: 02/16/2023 3. A review of the above listed patient final reports revealed the facility performed and reported seamen analysis on the following dates: Patient Accession #: 490653, final report date: 01/18/2023 Patient Accession #: 495276, final report date: 01/20/2023 Patient Accession #: 495024, final report date: 01/20/2023 Patient Accession #: 496499, final report date: 01/20/2023 Patient Accession #: 501743, final report date: 02/17/2023 4. During an interview on 03/24/2023 at 11:48 am, the Laboratory Director, after review of records, confirmed the above findings.

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 manufacturer's instructions, review of laboratory policies, direct observations, patient test records, laboratory records, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing hematological specimen (spermatozoa) smears for 5 of 5 patients in 2023 (random review January through February). Findings: 1. Review of "Harleco Hemacolor Stain Set" package insert revealed: "Procedure 1. Transfer each solution into a Coplin jar or staining trough and keep covered when not in use. 2. Prepare slides as indicated under Sample material section. 3. Immerse slide five times for one second each time into Solution 1. Allow the excess solution to drip off. 4. Immerse slide for one second each time into Solution 2, remove and hold in air for one second. Repeat 3 times. Allow the excess solution to drip off. 5. Immerse slide for one second each time into 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. 7. Allow to dry ..." 2. Review of the laboratory's policy "Morphology Staining" revealed: "6. Procedure 1. Confirm patient/specimen identification. Label slide with patient ID number, date of birth and date of procedure. Initial labels as they are used. 2. Slides must be immersed and moved into the solutions; simple immersion alone yields inadequate staining results. 3. Reagent 1 (Hemacolor Solution 1): 5 x 1 second. 4. Reagent 2 (Hemacolor Solution 2): 3 x 1 second. 5. Reagent 3 (Hemacolor Solution 3): 6 x 1 second. 6. Rinse under distilled water. 7. Allow slide to air dry." The laboratory's policy did NOT coincide the manufacturer's instructions. 3. During a tour of the laboratory on 03/24/2023 at 9:05 am, the surveyor observed three staining jars with solutions 1, 2 and 3 on the counter next to the sink. The surveyor asked testing person-3 (TP-3) to explain the laboratory's procedure for staining hematological specimen smears. TP-3 stated that each slide was dipped fifteen times in each of the three staining jars and then were rinsed off using tap water. The laboratory's practice did not coincide with the manufacturer's instructions or the laboratory's written policy. The laboratory failed to

follow manufacturer's instructions for staining hematological specimen smears. 4. A random review of patient test records revealed the following patients had hematological specimen smears performed in January through February 2023: 01/18/2023 Patient Accession #: 490653 01/20/2023 Patient Accession #: 495276, 495024, 496499 02/17/2023 Patient Accession #:501743 5. Review of laboratory records revealed the laboratory had an annual test volume of 503 hematological specimen smears. 6. During an interview on 03/24/2023 at 11 am, the Laboratory Director confirmed the laboratory failed to follow manufacturer's instructions for the staining of hematological specimens.