Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0961590	03/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Ctr For Reproductive Health,	700 S Mesa Hills, El Paso, 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 onsite survey conducted 03/19/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, quality control (QC) records, and confirmed in interview, the laboratory failed to retain one of two quality control instructions for use (IFU) that documented the acceptable concentration for two levels, a high and low count vial, of "Accu Beads" used in daily quality control for manual sperm counts. The findings included: 1. Review of the laboratory policy titled "Quality Control For Semen Analysis", section "III Procedure" stated the following: "15. Check the concentration you calculated with the concentration range listed for each vial of Accu Beads (This is shown both on the box and on the vial of Accu Beads). If your count is out of range, you must re load the Hemocytometer." 2. Review of the laboratory QC records titled "Daily QC ACCU - Beads & SA Procedures" included the following lot numbers of QC in use: August 26, 2022 - November 31, 2023 QC Beads In-Use: Low Count Vial Lot # 211410181, High Count Vial Lot # 211712351, Vials Expiration: December 2023 Surveyor asked for the IFU, or a photocopy of the box, for the low-count vial lot # 211410181 and the high-count vial lot # 211712351, that included the acceptable concentration range used to assess the acceptability of documented QC and none was provided. 3. In an interview on 3/19/2024 at 15:15, in the laboratory, testing personnel (TP) 1 confirmed that the laboratory failed to retain the documentation of the QC lot acceptable concentration range.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory test records, and confirmed in interview, the laboratory policy for semen analysis (SA) did not include the centrifugation speed and time necessary for the processing of SA specimens with the absences of sperm on the initial wet prep microscopy examination for two of two patients reviewed from April 2023. The findings included: 1. Review of the laboratory policy titled "Basic Semen Analysis" had the following instructions: "IMPORTANT NOTE: If no sperm is seen in the preliminary wet prep slide, repeat preparation of wet prep at least once to confirm the absence of sperm. Centrifuge ejaculate using warmed sperm wash media and remove supernatant. Prepare a wet prep from the precipitate pellet. Observe at least 25 fields. If sperm cells are present, estimate the concentration of cells. If no sperm is found, be sure to record this in the comments of the SA appointment form and fill out each section of SA appointment for accordingly." Surveyor asked at what speed and time specimen would be processed at for the above instance and testing personnel (TP) 1 stated that the laboratory washes SA at 1200 RPM for 5 minutes. 2. Review of laboratory SA worksheets in April 2023 included the following two patients with no sperm observed in the preliminary wet prep slide review: Account Number, Date of Service 16462, 4/13/2023 16488, 4/24/2023 3. In an interview on 3/19/2024 at 15:10 hours, in the laboratory, TP1 confirmed that the centrifugation speed and time were not included in the "Basic Semen Analysis" laboratory policy for specimens where no sperm is seen in the preliminary wet prep slide.