Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0924696	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Shady Grove Fertility - Walter Reed	8901 Wisconsin Ave, Bldg 10, 2nd Floor, Suite 2104, Bethesda, MD	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not document that the procedures were approved by the laboratory director at the Bethesda location. Findings: 1. The laboratory andrology procedures showing the director's approval was not included in the listing of laboratory locations (CLIA certificate numbers) and the corresponding approval by the director. 2. This was confirmed during the exit interview with the General Supervisor at 1:17 PM on the afternoon of the onsite survey.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not ensure that the standard operating procedure manual (SOPM) was up to date with testing procedures performed in the andrology laboratory. Findings: 1. The SOPM had a procedure for the Leucoscreen Plus test kit and procedures for documenting Wright's stain quality control checks even though the laboratory was not performing these tests. 2. The written quality control procedure for andrology testing states that the laboratory uses

	accu-beads as the quality control reagent for checking the sperm count test, but the laboratory was using Scopescreen QC-Beads. 3. This was confirmed during the exit interview with the General Supervisor at 1:17 PM on the afternoon of the onsite survey.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not follow manufacturer's instructions for the "Scopescreen QC-Beads" to perform quality control (QC) checks for the sperm count test. Findings: 1. The manufacturer's written procedure for QC-Beads: "Procedure for Manual Counting of QC-Beads" states that the laboratory should perform two separate counts each "using a fresh aliquot of beads" and to "compare the two results. If the results are within 10% of each other, then average the two counts." "The average count should be within the range of the Expected Values." 2. Record review showed that only one QC result was documented for each level of QC-Beads QC, per the general Supervisor (GS). 3. During an interview at 11:20 AM the GS stated that testing personnel do not perform duplicate counts when performing QC.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not include two controls each day of patient testing for andrology testing. Findings: 1. The laboratory performs sperm counts using the Makler chamber. The laboratory quality control reagents consisted of two levels of a known concentration of latex beads (level 1 and level 2) to check the sperm count. The laboratory tested level 1 for the first part of each month and then tested level 2 for the second part of the month each day of patient testing. The laboratory did not use both levels of quality control reagent each day of testing. 2. The laboratory did not cite references or provide an individualized quality control plan for the variances described above (numbered cites 1 and 2). 3. This was confirmed during the exit interview with the General Supervisor at 1:17 PM on the afternoon of the onsite survey.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director did not document that testing staff reviewed written andrology procedures. Findings: 1. The record (laboratory procedure review by department employees) was not completed as testing staff did not sign that they reviewed the andrology test procedures. 2. This was confirmed during the exit interview with the General Supervisor at 1:17 PM on the afternoon of the onsite survey.