Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2012836	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Washington Reproductive Laboratories	2531 Cowan Blvd, Fredericksburg, VA	

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 CLIA recertification survey was conducted at Washington Reproductive Laboratories on May 15, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
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 the review of the laboratory's "Quality Management Program", quality control (QC) records, patient records and interview with Testing Personnel A (TP A), the laboratory failed to perform QC procedures each day of patient testing for sperm counts for twelve (12) of thirty-one (31) days from June 1, 2017 to May 15, 2019 when performing testing for fifteen (15) patients. Findings include: 1. Review of the laboratory's "Quality Management Program" revealed the following: "General Information; Quality Control: Accu-beads (sperm quality control product) solution for both low and high levels is performed at room temperature to validate the accuracy of sperm counting method." 2. A review of the "Daily Quality Control Check Cell-Vu /Leja slides: Accu-Beads" log and patient records from June 1, 2017 to May 15, 2019 (a total of 31 days of testing) revealed the laboratory failed to perform QC when testing patients on: 08/17/17 patient number F-255, 08/31/17 F-256, 09/21/17 F-257, 09/28/17 F-258, 10/26/17 F-259, 12/14/17 F-261, 04/19/18 F-266, and F-267, 06/06 /18 F-273, 06/07/18 F-274, and F-275, 06/21/18 F-276, and F-277, 07/05/18 F-278, 07 /12/18 F-280, A total of 12 days with no QC and 15 patients reported. The surveyor

	requested QC documentation for the above listed dates when the laboratory did not perform QC while reporting 15 patients. The laboratory provided no documentation to review. 3. In an exit interview with the TP A at approximately 12:00 PM, TP A confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Quality Management Plan", quality control (QC) records, patient records, and interview with Testing Personnel A (TP A), the laboratory failed to establish a policy to identify and address analytic issues within the specialty of hematology (Cross Reference D 5447). Findings include: 1. Review of the the laboratory's "Quality Management Plan", quality control (QC) records, and patient test records revealed no documentation of QC procedures each day of patient testing for sperm counts for twelve (12) of thirty-one (31) days from June 1, 2017 to May 15, 2019 when performing testing for fifteen (15) patients. 2. Review of the "Quality Management Plan" signed by the laboratory director (no date provided) revealed no statement of a mechanism used by the laboratory to monitor and address QC issues in the specialty of hematology. The surveyor requested documentation of the laboratory director's review of QC for sperm counts. The laboratory provided no documentation for review.. 3. In an exit interview with the TP A at approximately 12:00 PM, TP A confirmed the findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the laboratory's "Quality Management Program", quality control (QC) records, patient records and interview with Testing Personnel A (TP A), the laboratory director failed to ensure the staff performed 2 levels of QC each day of patient testing for sperm counts for twelve (12) of thirty-one (31) days from June 1, 2017 to May 15, 2019 when performing testing for fifteen (15) patients (Cross Reference D5447).