Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2012836	05/16/2023
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 on-site CLIA recertification survey was conducted at Washington Reproductive Laboratories on May 16, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 C.F.R. part 493 CLIA Regulations. The specific deficiencies are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5200 - 42 C.F.R. 493.1230 Condition: General Laboratory Systems; D6076 - 42 C.F.R. 493.1403 Condition: High Complexity Laboratory Director.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of the laboratory's 2021 Statement of Deficiencies Form CMS-2567 plan of correction (POC), Quality Management records, proficiency testing (PT) records, accuracy verification records, lack of documentation, and interviews, the laboratory failed to: 1. perform twice annual verification of accuracy for semen analysis and adhere to their September 2021 POC in calendar year 2022 (See D5217 **REPEAT DEFICIENCY**); and 2. follow their Quality Management (QM) policy and September 2021 Plan of Correction for the nineteen (19) of the twenty (20) months reviewed from October 2021 through May 16, 2023 (See D5291). .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, Proficiency Testing (PT) records, accuracy verification records, 2021 Centers for Medicare and Medicaid Services (CMS) 2567 Statement of Deficiencies/Plan of Correction (POC), lack of documentation and interview, the laboratory failed to verify the accuracy of their complete semen analysis panel testing twice annually in calendar year 2022. Findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing Procedure (PT) Policy", with statements: "D. Alternative Performance Assessment-Alternative Assessment is performed on: Pre-stained Slides for Sperm Morphology; Semen Analysis..." and F. PT Procedure (COM.01000) - 2. Proficiency testing through AAB is conducted twice a year for andrology and embryology. - a. For andrology proficiency testing we are enrolled for sperm count and sperm morphology." 2. Review of the laboratory's Proficiency testing (PT) and accuracy verification records revealed a lack of documentation of the "twice a year" accuracy verification for semen analysis in calendar year 2022. The surveyor requested to review documentation of the "twice a year" accuracy verification for calendar year 2022. The laboratory provided no documentation for review. 3. Review of the laboratory's 2021 CMS-2567 Statement of Deficiencies/Plan of Correction (signed by the laboratory director on 10/08/2021) revealed a statement, "4. The testing personnel who perform the semen analysis will completed an on-site bi-annual testing comparison of sperm count and sperm motility with another testing personnel or supervisor at the Fredericksburg Andrology lab. 5. Records of the bi-annual testing comparison will be recorded on the same form used for Annandale comparisons, and will be reviewed and signed by the laboratory director annually." The surveyor requested to review documentation of the "on-site bi-annual testing comparison" for calendar year 2022. The laboratory provided no documentation for review. 4. In an exit interview with the laboratory director and senior embryologist on May 16, 2023, at approximately 1:30 PM, the findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, 2021 Centers for Medicare and Medicaid Services (CMS) 2567 Statement of Deficiencies/Plan of Correction (POC), Quality Management (QM) records, Proficiency Testing records, accuracy verification records, lack of documentation, and interviews, the laboratory failed to follow their Quality Management (QM) policy and September 2021 Plan of Correction for the nineteen (19) of the twenty (20) months reviewed from October 2021 through May 16, 2023. The findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Management General Laboratory Systems", with the following statements, "WFC (Washington Fertility

	Clinic) Laboratory monitors and evaluates the overall quality and corrects identified problems in the following general laboratory systems: Employee competency, laboratory safety, confidentiality of patient information, document control, complaint investigations, communications, specimen identity and integrity, Proficiency testing, and General laboratory systems quality management." and "C. Assessment of QM Program Implementation (GEN.20326)--WFC conducts and records the minutes to quality management meetings. Results of the assessment are communicated to appropriate lab personnel (Technical Supervisor, Director). The following activities are reviewed: Performance of quality indicators (see GEN.20316: Pre-analytic, analytic and post-analytic sections in this QM Manual); Corrective Actions for lack of quality indicator performance; reports in Corrective Action Manual (GEN.20318); Follow-up with corrective/preventive action (GEN.20310)." 2. Review of the laboratory's 2021 CMS-2567 Statement of Deficiencies/Plan of Correction (signed by the laboratory director on 10/08/2021) revealed a statement, "3. A monthly meeting will take place between all testing personnel, supervisory staff, and the lab director...4. If deficiencies are identified during the monthly meetings and corrective action is required, both the supervisor and the laboratory director will be responsible for continual monitoring of corrective action until the deficiency is rectified." 3. Review of the laboratory's QM records revealed a document, "WFC QM Fredericksburg Meeting Minutes" dated 10/13/2021. Listed on the document were "Other Topics-Immediate lab issues to be addressed, Equipment, PT Testing, Competency Assessment, Alarm System, Cryoinventory, Daily QC Review, Success Rates, QM program effectiveness. Discussed competency testing and twice-verification assessments--Determined that twice-verification assessment would be conducted twice; Comparisons would be conducted for accuracy verification between two testing personnel for procedures performed at Fredericksburg: sperm count and motility." Each topic was marked with a check-mark. No further QM monitoring documentation was noted. The surveyor requested to review QM monitoring documents from November 2021 to May 16, 2023. The laboratory provided no documents to review. 4. In an exit interview with the laboratory director and senior embryologist on May 16, 2023, at approximately 1:30 PM, the findings were confirmed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, accuracy verification records, Centers for Medicare and Medicaid Services (CMS) Statement of Deficiencies /Plan of Correction Form (CMS-2567), CMS Laboratory Personnel Report form (CMS-209), laboratory personnel files, quality assurance (QA) reports, lack of documentation, and interviews, the laboratory director failed to: 1. ensure the laboratory's established quality management policy was maintained from November 2021 until the date of the survey on May 16, 2023. See D6094. 2. identify the lack of initial training and semiannual competency evaluation documentation for two new testing personnel in calendar year 2022. See D6102.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, accuracy verification records, Centers for Medicare and Medicaid Services (CMS) Statement of Deficiencies /Plan of Correction Form (CMS-2567), CMS Laboratory Personnel Report form (CMS-209), laboratory personnel files, quality assurance (QA) reports, lack of documentation, and interviews, the laboratory director failed to ensure the laboratory's Quality Management policy was maintained from November 2021 until the date of the survey on May 16, 2023. See D5217-REPEAT DEFICIENCY, D5291, and D6102.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, laboratory policy and procedure manual, lack of documentation, and interviews, the laboratory director (LD) failed to follow established policy and ensure the initial training/competency and semi-annual competency evaluation was performed for two (2) of 2 new testing personnel responsible for performing high complexity semen analysis in calendar years 2021 and 2022. The findings include: 1. Review of the CMS-209 form with the senior embryologist, during an entrance interview on May 16, 2023 at approximately 12:00 PM, revealed the laboratory director (LD) functions as the Technical Supervisor and identified 2 new testing personnel (TP) responsible for performing semen analysis since the last inspection in September 2021. (See Personnel Code Sheet.) 2. Review of the laboratory personnel file for TP A revealed TP A was hired on 11/8/2021. The surveyor requested to review the initial training and semi-annual competency assessment documentation for TP A. The laboratory provided documentation of TP A's semi-annual competency completed and signed by the LD on 6/30/2022. The laboratory provided no documentation of TP A's training and initial competency for review. 3. Review of the laboratory personnel file for TP B revealed TP B was hired on 6/27/2022. The surveyor requested to review the initial training and semi-annual competency assessment documentation for TP B. The laboratory provided documentation of TP B's initial training/initial competency completed and signed by the LD on 7/15/2022. The laboratory provided no documentation of TP B's semi-annual competency. 4. Review of the laboratory's policies and procedures revealed the following statements: "II. Personnel Training (GEN.55500)-WFC (Washington Fertility Clinic) ensures all laboratory personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job. Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for

	proper test performance." and "For non-waived testing: During the first year of an individual's duties, competency must be assessed at least semi-annually." 5. In an exit interview with the laboratory director and senior embryologist on May 16, 2023, at approximately 1:30 PM, the findings were confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, laboratory policy and procedure manual, lack of documentation, and interviews, the technical supervisor failed to follow established policy and perform annual competency assessment evaluations for one (1) of one testing personnel responsible for performing high complexity semen analysis in calendar year 2022. The findings include: 1. Review of the CMS 209 form revealed Testing Personnel (TP) A performed high complexity testing. 2. Review of TP A's personnel file revealed TP A was hired on 11/8/2021(See Personnel Code Sheet). TP A's file lacked documentation of a 2022 annual competency. The surveyor requested to review documentation of TP A's 2022 annual competency. The laboratory provided no documentation to review. 3. Review of the laboratory's policy and procedure manual revealed a policy, "Competency Assessment of Testing Personnel", that stated "After an individual has performed his/her duties for one year, competency must be assessed at least annually." 4. In an exit interview with the laboratory director and senior embryologist on May 16, 2023, at approximately 1: 30 PM, the findings were confirmed.