Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0927262	01/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ccrm Virginia Beach	448 Viking Dr - Suite 100, Virginia Beach, 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 CCRM Virginia Beach on January 24, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D5200 -42 CFR. 493.1230 General Laboratory Systems.
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 a review of proficiency testing (PT) records, quality assurance (QA) policies, lack of documentation, and interview, the laboratory failed to verify twice annual accuracy of patient sperm count testing by Makler Counting Chamber per procedure and quality assessment protocols in calendar years 2022 and 2023. See D5217 (repeat deficiency).
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 andrology laboratory's proficiency testing (PT) records, quality assurance (QA) policies, lack of documentation, and an interview, the laboratory failed to verify twice annual accuracy of patient sperm count testing for twenty-four (24) of 24 months reviewed (timeframe February 2022 to the date of the inspection on 1/24/24). *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's American Association of Bioanalysts (AAB) and Wisconsin State Laboratory of Hygiene (WSLH) PT documentation in calendar year 2022 to the date of survey on 1/24/24 (five events) revealed the following one performance score report for Sperm Count: 2023 WSLH Off Schedule Proficiency Testing Evaluation Sperm Count Module 3200: 50% Unsatisfactory (specimen SP3 graded as Pass, specimen SP4 graded as Fail/incorrect response). The inspector requested to review additional accuracy verification for sperm count by Makler Counting Chamber for calendar year 2022 and 2023. No additional records were available for review. 2. Review of the laboratory's procedures revealed that the facility utilized AAB Proficiency Testing for accuracy verification that outlined "for sperm count (Makler Counting Chamber), motility, sperm morphology, and embryo grading, IVF culture media, and microscopy twice annually -internal audit will be performed when results are not graded by AAB or unsatisfactory". 3. Review of the laboratory's procedures revealed protocols for quarterly quality assurance audit reviews which included /outlined proficiency testing review of results and corrective action documentation. No records of additional sperm count accuracy determinations by Makler Counting Chamber were noted in the audit reports. 4. An interview with the laboratory's lead embryologist on 1/24/24 at approximately 1:00 PM confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of procedures, maintenance logs, lack of documentation, and interview, the laboratory failed to document twice annual function checks, per policy, for centrifuge speed -revolutions per minute (RPM) to verify acceleration (g) for one (1) Dynac 3 centrifuge utilized in the andrology laboratory in calendar years 2022 and 2023 . Findings include: 1. Review of the laboratory's Andrology Maintenance Procedure manual revealed the following protocol instructions: Maintenance Procedure- Centrifuge: "Speed and Timer Calibration to be performed twice per year-Tachometer check at 1600 RPM (should read +/_ 5 %). " 2. Review of the laboratory's Andrology Lab Procedure manual revealed the following protocol instructions: Sample Preparation and Handling Conditions-Simple Sperm Wash: "Perform sperm count and motility as detailed in Semen Analysis procedure, record results, place 1.0-1.5 ml of semen into a labeled conical tube, add 2.0 ml warmed mHTF, use sufficient number tubes to ensure entire sample is processed, mix well, centrifuge 8 minutes at

	300g, remove pellet and cloudy layer using a sterile transfer pipet, add pellet to labeled 2 ml tube of mHTF, combine all pellets in a single tube, mix well, centrifuge for 8 minutes at 300g." 3. Review of the laboratory's maintenance documentation for the survey timeframe of February 2022 to 1/24/24 revealed one record of RPM verification of the andrology laboratory's Beckton-Dickinson Dynac 3 centrifuge (Serial Number 4160006) by Controlled Conditions Corporation field service dated 1 /15/24 verification at 1600 with timer check of 5 minutes. 4. The inspector requested to review documentation of additional calibration records for the Dynac 3 for the procedural requirement of 300 g and/or maintenance procedure requirement of 1600 RPM during the twenty-four month review timeframe (February 2022 to 1/24/24). No records were available. 5. An interview with the laboratory's lead embryologist on 1/24 /24 at approximately 1:00 PM confirmed the above findings.