Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0927262	02/17/2022
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 The New Hope Center for Reproductive Medicine on February 17, 2022 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:
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 proficiency testing (PT) records, quality assurance (QA) policies, and an interview, the laboratory failed to verify twice annual accuracy of sperm motility testing in calendar year 2021. Findings include: 1. Review of the laboratory's American Association of Bioanalysts (AAB) PT documentation from 2020 to the date of survey on 2/17/22 (four events) revealed the following two (2) unsatisfactory performance scores for Sperm Motility: 2021 Embryology, Andrology, and Fetal Module 1: 50% (specimen 1 graded as incorrect response, Specimen 2 noted by AAB as not graded due to lack of participant consensus), 2021 Embryology, Andrology, and Fetal Module 2: 50% (Specimen 1 graded as incorrect response). The inspector requested to review additional accuracy verification for sperm motility testing for calendar year 2021. 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 for sperm count, motility, sperm morphology, and embryo grading twice annually that outlined "internal audit will be performed when results are not graded by AAB or unsatisfactory". 3. An interview with the laboratory's lead embryologist on 2/17/22 at approximately 1:00 PM confirmed the above findings.

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 a tour of the laboratory, review of procedures, pipette calibration records, and an interview, the laboratory director (LD) failed to update an approved posted laboratory maintenance schedule/protocol for pipette calibration as reviewed on the date of the inspection, February 17, 2022. Findings include: 1. During a tour of the laboratory on 2/17/22 at approximately 10:30 AM, the inspector noted six (6) Gilson Pipetman single channel pipettes in use and racked/stored in the laboratory safety hood. The inspector noted calibration stickers by Rainin Technical Services dated for calendar year 2018. 2. Review of a posted IVF Laboratory Maintenance Schedule revealed protocols/procedure for annual pipette calibration and service. 3. Review of available pipette calibrations revealed Rainin service reports for the 6 pipettes outlined above dated in calendar year 2017-2018. No additional calibration records were available for review. The embryologist stated at approximately 12:00: "We no longer send the pipettes out for calibrations. I think that was discontinued in 2019." The inspector requested to review the IVF Laboratory Maintenance Schedule procedure changes approved by the LD. The embryologist stated at approximately 12: 10: "I will get the director to modify the written procedure posted in the lab to reflect the procedure change." 4. An interview with the laboratory's lead embryologist on 2/17 /22 at approximately 1:00 PM confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of daily temperature logs and an interview, the laboratory failed to document corrective action when the in vitro fertilization (IVF) warming oven temperatures were outside the acceptable limits for two (2) days in 2020 and five (5) days in 2021. Findings include: 1. Review of the laboratory's Quality Control IVF Laboratory Temperature Logs for the randomly selected months of May 2020, September 2021, November 2021, and December 2021 revealed the IVF warming oven temperatures were recorded outside of the acceptable limits of 33-38 degrees Celsius (C) on the following seven (7) dates: 9/25/21, 11/16/21, 11/23/21, 12/15/21, 12 /16/21, 5/24/20, and 5/25/20. 2. Review of corrective action documentation revealed no action was recorded for the IVF warming oven temperatures on the 7 dates outlined above. The inspector inquired regarding the protocols for documentation of corrective action for outlier temperatures. The embryologist stated at approximately 12:30 PM: "We adjustment the equipment if the temperature is out of range and apparently the staff forgot to update the log on these dates." 3. An interview with the laboratory's lead embryologist on 2/17/22 at approximately 1:00 PM confirmed the above findings