Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0707956	(X3) Date Survey Completed 08/10/2022
Name of Provider or Supplier Rwhm South Jersey Fertility Center Marlton	**Street Address, City, State** 400 Lippincott Drive #130, Marlton, NJ	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the General Supervisor (GS) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) who perform Semen Analysis and Endocrinology testing on the date of survey. The findings include: 1. The CA was not performed on two out seven TP in the calendar years, 2020, and 2021. 2. The GS confirmed on 8/10/22 at 10:20 am the laboratory did not follow the CA procedure.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS) the laboratory failed to review and evaluate results when they received an unacceptable score in Sperm Count tests performed with the American Association of Bioanalysts (AAB), for event S1-2021. The findings include: 1. The laboratory received an 0% grade for Sperm Count Video. 2. There was

	no documented evidence that the laboratory investigated the failure. 3. The GS confirmed on 8/10/22 at 11:45 am that the laboratory did not review and document an evaluation of unacceptable PT results.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the The Bioscreen QC-Beeads Instructions For Use (IFU), Sperm Count Quality Control log and interview with the General Supervisor (GS), the laboratory failed to follow the IFU for "Manual Counting of QC-Beads" at the time of survey. The findings include: 1. The IFU stated "8. Compare the two results. If the results are within 10% of each other then average the two counts" 2. There was no documented evidence that the aforementioned procedure was being followed. 3. The GS confirmed on 8/10/22 at 12:50 pm that the laboratory did not follow the IFU.
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 the lack of Quality Control (QC) records and interview with the General Supervisor (GS)l, the laboratory failed to perform and document QC on each day of patient testing for Semen Morphology Analysis on the date of the survey. The GS confirmed on 8/10/22 at 2:00 pm that the laboratory did not perform QC on each day of patient testing.
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 surveyor review of Personnel Records (PR) and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the education and training records were available on the date of the survey. The finding includes: 1. Education and training records were not available for one out of seven TP. 2. The GS confirmed on 8/10/22 at 10:30 am that all education records were not available.