Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1088057	06/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rwhm South Jersey Fertility Center Sewell	570 Egg Harbor Road, Sewell, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory lacked work and graded result records for all American Associates of Bioanlalysts (AAB) PT events for semen analysis tests in the event AAB-2S-2023. Findings include: 1. Review on 6/26/24 of PT records revealed a lack of work and graded result records for AAB PT event AAB-2S-2023 for semen analysis. 2. The TP confirmed on 6/26/24 at 11:35 am that work and graded result records were not available for the PT event mentioned above.
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 QC-Beads Manufacture package insert (MPI), Quality Control (QC) records and interview with the Tenting Personnel (TP), the laboratory failed to follow the MPI for "Procedure for Manual Counting of QC-Beads", on the date of survey 6/26/24. Findings include: 1. Review on 6/26/24 of the "Procedure for the Manual Counting of QC Beads" revealed: a) count the beads using a standard counting procedure for counting sperm 1 Invert the bottle several times to suspend the HAS QC-Beads 2. Using a pipette, remove the volume recommended for the counting chamber you are using. 3. Pipette the bead suspension into the counting chamber. 4. Immediately recap the bottle. 5. Wait about 5 minutes to allow the beads to stop moving and them observe using a microscope 6. Count at least 200 beads. 7. Calculate the concentration of bead according to the counting chamber Manufactuers instructions. 8. Repeat steps 1-7 using fresh aliquot of beads. 9. Compare the two results. If the results are within 10% of each other, then average the two counts. 2. A review of QC records revealed steps 8 and 9 were not performed. 3. The TP confirmed on 6/26/24 at 11:10 am that the MPI was not followed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify QC-beads Lot 46-723 before use for Semen Analysis (SA) tests on the date of survey 6/26/24. Findings include: 1. Record review on 6/26/24 of semen analysis QCV records revealed a lack of verification documentation of QC-beads Lot 46-723 before use. 2. The TP confirmed 6/26/24 at 11:15 am that QC material was not verified before putting in use.
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 surveyor review of the Procedure Manual (PM) and interview with Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems on the date of survey 6/26/24. Findings include: 1. The laboratory failed to have a procedure to verify new lots of semen analysis controls before they were put in use. 2. The TP confirmed on 6/26/24 at 11: 40 am that the laboratory failed to have a procedure to verify new lots of semen analysis controls before they were put in use.