Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2257073	05/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Conceive Nj	1599 State Route 34, Farmingdale, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to have a procedure for Quality Control Verification (QVC) for Endocrinology testing from 3/31/22 to the date of survey. The LD confirmed on 5/28/24 at 12:30 pm that the laboratory failed to have the above mentioned procedure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of progesterone sample diluent and interview with the Laboratory Director (LD), the laboratory failed to discard expired progesterone sample diluent Lot #D45C34/48 from 3/31/24 to the date of survey. The LD confirmed on 5/28/24 at 10:30 am that the laboratory failed to discard expired progesterone sample diluent

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: A) Based on surveyor review of Five Final Reports (FR) for Semen Analysis testing and interview with the Laboratory Director (LD), the laboratory failed to have Reference Interval (RI) for Potential of Hydrogen (PH) on the FR from 3/31/22 to the date of survey. The LD confirmed on 5/28/24 at 1:00 pm the laboratory failed to include RI for PH tests. B) Based on surveyor review of the FR, Manufactuers package inserters (MPI), and interview with the Laboratory Director (LD), the laboratory failed to ensure that the RI were accurate for analytes run on the Tosho A1A-369 form 3/31/22 to the date of survey. The findings include; 1. The LD stated that RI's were taken from the Manufactuers reagent inserts. 2. The RI one the FR for Luteinizing Hormone (LH) was 5.0-25.0 3. The MPI stated the RI for LH as follows: a) Follicular phase 1.7-163.3 mLU/mL b) Mid-Cycle 4.1-68.7 mLU/mL c) Luteal Phase 0.5-19.8 mLU/mL d) Postmenopasual 14.4-62.2 mLU/mL 4. The RI one the FR for Follicle-stimulating hormone (FSH) was 4.7-21.5 5. The MPI stated the RI for FSH as follows: a) Follicular phase 4.35-11 mLU/mL b) Mid-Cycle 3.6-20.6 mLU /mL c) Luteal Phase 1.5-10.8 mLU/mL d) Postmenopasual 36.6-168.8 mLU/mL 6. The RI one the FR for Estradiol (E2) was 4.7-21.5 7. The MPI stated the RI for E2 as follows: a) Follicular phase 1.7-13.3 mLU/mL b) Mid-Cycle 4.1-68.7 mLU/mL c) Luteal Phase 0.8-19.8 mLU/mL d) Postmenopasual 14.4-62.2 mLU/mL 8. The LD confirmed on 5/28/24 at 12:30 am that the laboratory failed to ensure the RI's were accurate.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS were adequate to perform Endocrinology tests performed on the Tosoh A1A-360 analyzer from 3/31/22 to the date of survey. The findings include: 1. The laboratory failed to perform a normal patient range study. 2. The LD confirmed on 5/28/24 at 11:15 am that not all PS were adequate.