Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0683204	07/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Diamond Institute	89 Millburn Ave, Millburn, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. 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 PT results obtained from the American Association of Bioanalysts (AAB) and College of American Pathologists (CAP) for Andrology in events performed in 2020 and 2021. The findings include: 1. The laboratory did not evaluate "Note 26" - educational challenge - response from CAP for the following: a. Sperm classification specimen SPCD-03D and SPCD-04D. 2. The laboratory did not evaluate "?" - lack of consensus - response from AAB for the following: a. Sperm Cell ID specimen 5, 1st event 2020. b. Sperm cell ID specimen 8, 2nd event 2020 3. The GS confirmed on 7/12//22 at 11: 00 am that the laboratory failed to evaluate the above mentioned coded results.
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), Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to follow the PM for

	Semen Analysis on 6/30/22 to the date of the survey. The findings include: 1. The PM stated under Semen Specimen Collection and Handling "If the sample is received greater than 1 hour from collection time, the sample will be processed, a physician will be notified and a notation in the patient's report will state the sample was collected greater than 1 hour from receipt". 2. FR, Accession # 063022-1, Account # 42015 had a collection time and date of 6/30/2022, 6:45 am and a report time and date o 6/30/2022 11:30 am. a. There was no evidence the physician was notified the sample was received greater than 1 hour from collection time. b. There was no notation on the FR that the sample was received greater than 1 hour from collection time. 3. The GS confirmed 7/12/22 at 2:00 pm that the laboratory did not follow the PM.
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 Bio-Rad Lyphocheck Immunoassay Plus Control Instructions For Use (IFU), observation of the Quality Control Material (QCM), Freezer, Freezer Temperature Logs (FTL) and interview with the Testing Personnel (TP), the laboratory failed to follow the IFU for Storage and Stability at the time of survey. The findings include: 1. The IFU stated "Reconstituted and Frozen: When reconstituted and stored tightly capped at -20 to -70 C this product will be stable as follows: - All analytes: 20 Day" 2. The freezer used to store QCM could not maintain a temperature range of -20 to -70 C. 3. There was no documented evidence that the aforementioned procedure was being followed. 4. The TP confirmed on 7/12 /22 at 12:50 pm that the laboratory did not follow the IFU.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Inserts, observation of the Quality Control material, and interview with the Testing Personnel (TP), the laboratory failed to put open and expiration dates on Endocrinology Control material run on the Cobas e411 analyzer on the date of survey. The TP confirmed on 7/12/22 at 12:50 pm the laboratory failed to put open and expiration dates on the control material.
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 the Quality Control (QC) material open dates and interview with the General Supervisor (GS), the laboratory use expired QC for Hematology tests run on the Sysmex XP-300 from 7/1/22 to the date of survey. The findings include: 1. Eightcheck-3WP controls Lot 21090710 expired 7/1/22. a. Eightcheck-3WP control material is stable for 14 days after opening. b. Eightcheck-3WP controls Lot 21090710 had an open date of 6/17/22. 2. Approximately 20 patients were run and reported. 3. The GS confirmed on 7/12/22 at 12:50 pm that the laboratory used expired QC.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Manufactures Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to follow the Manufacturer's Specifications (MS) on performing QC for Follicle Stimulating Hormone (FSH) and Human Chorionic Gonadotropin (HCG) run on the COBAS e411 analyzer on the date of survey. The findings include: 1. The laboratory had QC values outside the ranges stated in the MPI as follows: a. The MPI stated the FSH level two QC range was 17.8 - 25.3 mIU/mL but the laboratory had 20.0 - 25.16 mIU/mL. b. The MPI stated the HCG level one QC range was 4.06 - 6.31 mIU/mL but the laboratory had 5.326 - 6.814 mIU/mL. c. The MPI stated the HCG level two QC range was 15.9 - 23.1 mIU/mL but the laboratory had 19.57 - 24.25 mIU/mL. d. The MPI stated the HCG level three QC range was 126 -179 mIU/mL but the laboratory had 150.8 -185.78 mIU/mL. 2. The TP confirmed on 7/12/22 at 1:15 pm that MS were not followed
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: Based on the surveyor review of the Final Reports (FR), Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have accurate Reference Interval (RI) for Endocrinology tests run on the Cobas e411 on the date of survey. The findings include: 1. A review of the FR revealed the IR for Estradiol (E2)

	did not match the PM as follows. a. E2 Follicular phase RI on the FR was 12.5 - 166.0 pg/mL but the PM stated 186-219 pmol/L or 50.6 - 59.6 pg/mL. b. E2 Ovulation phase RI on the FR was 85.8 - 498.0 pg/mL but the PM stated 408-544 pmol/L or 111 - 148 pg/mL. c. E2 Luteal phase RI on the FR was 43.8 - 211.0 pg/mL but the MA stated 327-419 pmol/L or 8 - 114 pg/mL. 2. The GS confirmed on 7/12/22 at 1:00 pm that laboratory failed to have accurate RI.