Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1058985	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Delaware Valley Institute Of	2950 College Drive Suite 2b, Vineland, 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 failed to maintain "Semen Analysis Report" for proficiency samples for the 1st and 2nd event in 2017 and the 1st event of 2018. The TP #1 listed on CMS form 209 confirmed on 7/31/18 at 10:00 AM that "Semen Analysis Report" records were not maintained for the aforementioned PT events. This deficiency was previously cited on the survey dated 7/26/2016. The Plan of correction for this deficiency was "Laboratory is now performing all Semen analysis counts, motility, and morphology at the Vineland location" there is no evidence that the PT is being performed in Vineland.
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 Testing Personnel (TP), the Technical Supervisor / Laboratory Director (TS /LD) failed to use the applicable elements to assess Semen Analysis testing on two out of two TP in the calendar years 2017 and 2018. The findings include: 1) The CA did not include Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. 2) The CA did not include Monitoring the recording and reporting of test results. 3) The CA did not include Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 4) The CA did not include Assessment of problem solving skills. 5) The CA did not include Direct observation of performance of instrument maintenance and function checks. 6) The TP #1 listed on the CMS form 209 confirmed on 7/31/18 at 1:35 pm that the TS/LD failed to use the applicable elements to assess CA.
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 Testing Personnel (TP), the laboratory failed to follow Sperm Motility Quality Assurance Procedures (SMQAP) at the time of survey. The finding includes: 1.The SMQAP stated "Twice a year, a discard semen sample is used to test the range of measurements among technical staff", and "The results are documented in the intra sperm motility QA log". a) The TP did not know about this procedure b) The laboraotry did not use the "Intra sperm motility QA" log. 2. The TP #1 listed on CMS form 209 confirmed on 7/31/18 at 11:30 am that the laboratory did not perform SMQAP twice a year.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor review of a lack of Maintenance Records and interview with the

	Testing Personnel (TP), the laboratory failed to perform or document calibration of pipettes and annual Microscope maintenance used in Semen Analysis from January 2016 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 7/31/18 at 11:00 AM that pipette calibration and Microscope annual maintenance was not performed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for manual entry verification from 6/19/14 to the date of survey. The TP #1 listed on CMS from 209 confirmed on 7/31/18 at 11:30 am that the laboratory had not established a manual entry verification procedure. This deficiency was previously cited on the last inspection cycle. The Plan of Correction for the deficiency was "Written policy and procedures addressing quality assessment are in place in section 3 and up of andrology manual. A copy of these sections are available upon request. New lab personnel are being properly trained". No procedure for manual verification was available for surveyor 7/31/18. There was no evidence that manual entry verification was being performed.