Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2152380	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Genomic Prediction Clinical Laboratory Inc	671b Us Highway One, North Brunswick, 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 Laboratory Director (LD), the laboratory failed to maintain work records for Preimplantation Genetic Screening PT provided by the American Associations of Bioanalysts (AAB) for 2 - 2018. The LD confirmed on 4/23/19 at 1:50 pm that work records were not maintained.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Logs and interview with the General Supervisor (GS), the laboratory failed to monitor and document the Temperature of the VWR incubator used for Molecular Genetic tests from 8/8/18 to the date of survey. The GS confirmed on 4/23/19 at 10:20 am that the laboratory did not document temperature of the incubator.
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 observation of reagents, solutions and interview with the General Supervisor (GS), the laboratory failed to put prepared and expiration dates on the reagents and solutions on the Genetitan MC used to perform Molecular Genetic tests at the time of the of survey. The GS confirmed on 4/23/19 at 1:45 pm the reagents and solutions in use were not labeled.
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 Molecular Genetic tests from 8/8/18 to the date of survey. The findings include: 1. The laboratory did not develop a plan or define acceptance criteria for PS. 2. Sample stabilty was not validated. 3. The LD confirmed on 4/23/19 at 2:30 pm that PS were not adequate.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with

	the Laboratory Director (LD), the LD failed to ensure that all PT results obtained from the American Association of Bioanalysts (AAB) were reviewed and evaluated by the appropriate staff in the calendar year 2018. The finding includes: 1. There was no review of AAB results for Preimplantation Genetic Screening in 2 - 2018. 2. The LD confirmed on 4/23/19 at 11:10 am that the laboratory did not review and evaluate PT results.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory Procedure Manual and interview with the Laboratory Director LD, the LD failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from 8/8/18 to the date of the survey. The LD confirmed on 4/23/19 at 1:45 pm that a QA program was not established.