Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2060633	07/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Ncsnj - Washington	66 East Washington Avenue, Washington, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 and interview with the Quality Risk Manager (QRM), the laboratory failed to perform and document Immunohematolgy QC on each day of patient testing from 2/23/22 to the date of the survey. The findings include: 1. The QC records reviewed showed that the lab did not perform positive and negative QC on the following dates: 2/23/22, 4/4/22, 4/12/22. 2. Approximatly six patients where run and reported. 3. The RQM confirmed on 7/28/22 at 2:30 pm that positive and negative QC were not run every day of patient testing.
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 surveyor review of Quality Control (QC) records and interview with the Quality Risk Manager (QRM), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Rhesus factor tests performed on EldonCards at the time of survey. The finding includes: 1. There was no documented evidence that Negative control lot HMN689492 was verified. 2. The QRM confirmed on 7/28/22 at 2:00 pm that the QC material was not verified before putting in use.