Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0116942	02/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Ncsnj - Morristown	196 Speedwell Ave, Morristown, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Quality Risk Manager (QRM), the laboratory failed to ensure that Testing Personnel (TP) who routinely perform Rhesus (Rh) testing participated in the American Proficiency Institute (API) PT events in the calendar years 2016 and 2017. The finding includes: 1. A review of PT results revealed only one out of three TP performed all PT events in 2016 and 2017. 2. The QRM confirmed on 2/8/18 at 1:30 pm that PT surveys were not performed by all TP.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview the Quality Risk Manager (QRM), the laboratory failed to retain work records for PT performed with the American Proficiency Institute for Rhesus (Rh) testing in the calendar years 2016 and 2017. The QRM stated on 2/8/18 at 1:10 pm that all PT records were not retained.
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 Quality Risk Manager (QRM), the laboratory failed to follow the procedure for Quality Control (QC) of Eldon Cards from 5/27/15 to the date of survey. The findings include: 1. The PM stated to "upon receipt of a shipment of Eldon Cards, check for possible damage during transportation and ensure the quality of the card by testing with red cells with and without the Rhesus (Rh) D antigen." 2. A review of the QC records revealed that the laboratory did not perform the above procedure. 3. The QRM confirmed on 2/8/18 at 2:10 pm that the PM was not followed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Quality Risk Manager (QRM), the laboratory failed to include all the required information on the FR from 5/25/15 to the date of survey. The finding includes: 1. A review of five Wet Mount/Potassium Hydroxide (KOH) FR revealed four out of five did not have the test result documented. 2. The QRM confirmed on 2/8/18 at 1:50 pm the FR did not have all the required information.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Quality Risk Manager (QRM), the Technical Consultant (TC) failed to evaluate the competency of two out of three Testing Personal (TP) in the calendar years 2016 and 2017. The finding includes: 1. The TC did not ensure Competency Assessment (CA) was performed by a qualified individual. a. TP #2 on CMS form 209 had a high school

	diploma but the CA on TP #1 and #3 who had a Bachelors and Associates degree respectively was performed by TP #2. 2. The QRM confirmed on 2/8/18 at 1:40 pm that the TC did not ensure who must perform CA.