Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0116942	(X3) Date Survey Completed 05/14/2019
Name of Provider or Supplier Planned Parenthood Ncsnj - Morristown	**Street Address, City, State** 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
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 2/8/18 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 5/14/19 at 2:10 pm that the PM was not followed. Note: This was cited on the previous survey done on 2/8/18. Plan of correction stated the laboratory would "perform QC on the date of receipt". QRM would monitor and ensure.
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 2/8/17 to the date of survey. The finding includes: 1. A review of ten patient FR revealed: a. Wet Mount/Potassium Hydroxide (KOH) - four out of five did not include the patient's result. b. Rhesus Factor (RH) - one of five did not have a result documented. c. Five of ten did not have the address of the laboratory location where test was performed. 2. The QRM confirmed on 5/14/19 at 1:50 pm the FR did not have all the required information. Note: This was cited on the previous survey done on 2/8/18. Plan of correction stated the "required medical record documentation for test reporting was reviewed with the provider. The Laboratory Director has put into place that in-house lab logs for documenting test results are placed on the front of the medical record to insure complete documentation. The center manager will review the logs daily."