

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0702157	<b>(X3) Date Survey Completed</b>  12/07/2021
<b>Name of Provider or Supplier</b>  Planned Parenthood Ncsnj-	<b>Street Address, City, State</b>  1323 Route 27, Franklin Twp, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a) Based on surveyor review of the Procedure Manual (PM) and interview with the Quality Risk Manager (QRM), the laboratory failed to follow their procedure for completing the "Rh Factor Test Log" (RFTL) from 7/16/20 to the date of survey. The findings include: 1. The RFTL policy require the "Internal control is present/negative" and "The name of the reagent, reagent lot number, reagent received date, reagent opened and expiration" is documented. 2. The RFTL procedures were not followed as follows: a. There was no documented confirmation the internal control was present /negative on 8/5/20, 8/13/20, 8/10/21, 9/29/21, 10/20/21, 10/12/21, 11/1/21 on the RFTL. b. The name of the reagent, reagent lot number, reagent received date, reagent opened and expiration was not documented 7/20/21 through 10/22/21 on the RFTL. 3. The QRM confirmed on 12/7/21 at 2:20 pm the aforementioned procedures were not followed. b) Based on surveyor review of the Procedure Manual (PM) and interview with the Quality Risk Manager (QRM), the laboratory failed to follow their procedure for completing the "Control Log for Rho (D) [RH Factor]" (CLR) from 11/16/20 to the date of survey. The findings include: 1. There was no documentation of both positive and negative control lot numbers and expiration dates on the CRL from 7/16 /20 until the date of survey. 2. Eldon Card RhD received date and lot number was not documented on the CLR from 11/16/20 through 12/12/20 3. Eldon Card RhD open date, expiration date, received date and lot number was not documented on the CLR</p>

from 1/11/21 through 2/7/21 4. Eldon Card RhD open date and lot number was not documented on the CLR from 2/8/21 through 4/3/21. 5. The QRM confirmed on 12/7/21 at 2:21 pm the aforementioned procedures were not followed.

**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 Immuno-hematology QC on each day of patient testing from 8/20/21 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: 8/20/21, 11/5/21, 11/17/21, 11/24/21, 11/30/21 2. Six patients were run and reported. 3. The QRM confirmed on 12/7/21 at 2:00 pm that positive and negative QC were not run every day of patient testing.

**D6070**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:  
Based on surveyor observation the Rh Factor Test Logs (RFTL), Control Log for Rho (D) [RH Factor] (CLR) log's and interview with the Quality Risk Manager (QRM), the TP failed to follow procedures for maintaining records of patient test results for RH factor at the time of survey. The findings include: 1. There was no documented confirmation the internal control was present/negative on 8/5/20, 8/13/20, 8/10/21, 9/29/21, 10/20/21, 10/12/21, 11/1/21 on the RFTL. 2. The name of the reagent, reagent lot number, reagent received date, reagent opened and expiration was not documented 7/20/21 through 10/22/21. 3. There was no documentation of both positive and negative control lot numbers and expiration dates on the CLR from 7/16/20 until the date of survey. 4. Eldon Card RhD received date and lot number was not documented on the CLR from 11/16/20 through 12/12/20. 5. Eldon Card RhD open date, expiration date, received date and lot number was not documented on the CLR from 1/11/21 through 2/7/21. 6. Eldon Card RhD open date and lot number was not documented on the CLR from 2/8/21 through 4/3/21. 7. The QRM confirmed on 12/7/21 at 2:30 pm that laboratory failed to follow laboratory procedures for maintaining records of patient test results.