

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0111811	(X3) Date Survey Completed 12/21/2021
Name of Provider or Supplier Planned Parenthood Of Northern, Central	Street Address, City, State 1171 Elizabeth Avenue, Elizabeth, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the survey review of Quality Control (QC) records and interview with the Office Manager (OM) the laboratory failed to retain the Manufacturers Pack Insert (MPI) for Negative Rhesus (Rh) factor control from January 2021 to the date of survey. The findings include: 1. There was no MPI for negative Rh QC for the following lots: a. HMN687680 b. HMN674223 c. HMN626695 d. HMN593186 e. HMN626695 2. The OM confirmed on 12/21/20 at 2:00 pm that MPI's were not retained.</p>