Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0668204	06/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pph Of Northern, Ctrl & Souther No New Jersey, Inc	800 West Main Street, Freehold, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Manufacturer Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to follow the MPI for Rhesus (Rh) factor test at the time of survey. The findings include: 1. The MPI and AL stated Eldon Bag RhD-25 "expires six month after first opening". 2. The laboratory did not put new expiration date on the Eldon bag and in AL. 3. The laboratory was not aware that expiration date shortens once Eldon bag is opened 4. The TP # 2 listed on CMS form 209 confirmed on 6/8/18 at 1:10 pm the laboratory failed to follow the MPI.