

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2060633	(X3) Date Survey Completed 01/19/2018
Name of Provider or Supplier Planned Parenthood Ncsnj - Washington	Street Address, City, State 66 East Washington Avenue, Washington, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control records, Quality Control (QC) material, and interview with the Quality Risk Manager (QRM), the laboratory used expired QC material for Rhesus (Rh) factor tests in July and October 2016 and January 2018. The findings include: 1. Bioreclamation Whole Blood Negative Control Lot # BRH1177317 expired on 7/21/16 and BRH1217875 expired on 10/13/16 but the laboratory ran samples on 7/23/16 and 10/15/16 accordingly. 2. The laboratory performed and reported 8 patient results during the above time frame. 3. The Rh positive control expired on 1/11/18 and the laboratory performed and reported 3 patient results after the expiration date. 4. The QRM confirmed on 1/19/18 at 10:35 am that the laboratory used expired QC.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p>

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 indicate all the required information on the FR from June 2015 to the date of survey. The findings include: 1. A review of ten final reports revealed one out of ten did not have the test result and one of ten did not have the date test was performed. 2. The QRM confirmed on 1/19/18 at 11:00 am the FR did not have all the required information.