

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0111832	(X3) Date Survey Completed 01/17/2018
Name of Provider or Supplier Women's Choice Of Bergen County Pa	Street Address, City, State 200 Grand Avenue, Suite 101, Englewood, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain a copy of all records for Rhesus factor test performed with the American Association of Bioanalyst for Q1, Q2 & Q3 2016. The finding includes: 1. The attestation statements were not signed by the Laboratory Director for PT events Q1, Q2 & Q3 2016 2. The TP confirmed on 1/17/18 at 10:15 am that all PT records were not maintained.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel</p>

who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Accession Logs (AL) and interview with the Testing Personal (TP), the laboratory failed to document the date of specimen collection for Rhesus factor test were performed from October to November 2017. The finding includes: 1. There were no dates recorded in the AL when patient testing occurred between 10/27/17 and 11/4/2017 on four separate days. 2. The TP confirmed on 1/18 /18 at 10:00 am that the laboratory did not document the dates patient testing was performed in the AL.