

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D1002531	<b>(X3) Date Survey Completed</b>  05/08/2018
<b>Name of Provider or Supplier</b>  Women's Health Care Pc	<b>Street Address, City, State</b>  87-16 Avon Street, Jamaica Est, NY	
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>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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's observation of the reagents located in the laboratory refrigerator and confirmed in an interview with the technical consultant and the two testing personnel, the laboratory failed to discard expired reagents. FINDINGS: The technical consultant and two testing personnel confirmed on May 8, 2018 at approximately 1:30 PM, the following expired reagents were stored in the refrigerator: a. ABX Pentra 400 CO2 calibrator Lot #60112554 expiration date 10/31/2017 b. Bio-rad Wash Solution 30X expiration date 4/30/2018</p>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the surveyor's review of the laboratory's Individual Quality Control Plan (IQCP), Quality Control Plan (QCP) and Quality Assessment (QA) procedures and confirmed in the interview with the technical consultant and the two testing personnel, the laboratory's QCP failed to include the type of external control material used for QC testing, frequency QC material is tested and the criteria for acceptability of the controls. FINDINGS: The technical consultant and the two testing personnel confirmed on May 8, 2018 at approximately 2:30 PM , the surveyor's findings that the laboratory failed to include the type of external control material used for QC, frequency QC material is tested and the criteria for acceptability for BD Affirm VPN QC . a. The BD Affirm VPN manufacturer requires a Trivalent swab to be tested with each new lot of PAC test cassettes. b. The laboratory director failed to establish the frequency and the criteria for acceptability for the QCP.