

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>09D2133202</p>	<p>(X3) Date Survey Completed</p> <p>03/30/2018</p>
<p>Name of Provider or Supplier</p> <p>Dc Medical Offices, Llc</p>	<p>Street Address, City, State</p> <p>6323 Georgia Avenue Nw, Suite 210, Washington, DC</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5551</p>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on an interview with the Laboratory's Operation Manager and the review of policies and procedures, manufacturer's instructions and patient test results on March 30, 2018 at approximately 11:30 AM, the laboratory's policies and procedures for Rhesus Factor (RhD) testing failed to include the laboratory's policy regarding testing for weak D (Du) when RhD test is negative. The findings included: Review of Bioclon the manufacturer of the of the Anti-D reagent revealed that red blood cells that test RhD negative may be further tested for Du, if desired. Although the Laboratory's Operation Manager indicated that testing for Du is not performed in this laboratory, review of the laboratory's procedure did not include information regarding its policy for not testing for Du. Review of patients' test results with negative RH also failed to state that the patients were not tested for Du.</p>