

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0721827	<b>(X3) Date Survey Completed</b> 02/08/2018
<b>Name of Provider or Supplier</b> Wellington S Tichenor Md	<b>Street Address, City, State</b> 642 Park Avenue, New York, 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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyors review of the laboratory's procedure manual and an interview with the laboratory testing person, the laboratory failed to have a complete procedure manual. Findings Include: It was confirmed by the laboratory testing person at approximately 11:00 AM on February 8, 2018 that the laboratory failed to have procedures for: 1) Twice annual verification of Nasal Smears; 2) describing the process of verifying; establishing and maintaining new assayed QC ranges.</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 a lack of a risk assessment evaluation procedure and an interview with the laboratory testing person, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) for Immunology testing. Findings Include: It was confirmed with the laboratory testing person on February 8, 2018 at approximately 11:15 AM, the laboratory failed to have a risk assessment (RA) plan for the Binding Site Human IgG, IgA & IgM Bindarid Radical Immunodiffusion Kit to include, Specimen, Test system, Reagent, Environment, and Testing Personnel.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on a lack of twice annual verification, laboratory procedures, and an interview with the laboratory testing personnel, the director failed to ensure that a quality assessment program was in place for hematology and immunology testing. Findings Include: It was confirmed with the laboratory testing personnel on February 8, 2018, at approximately 11:15 AM that the laboratory's failed to have a complete quality assessment program for the following: 1) Twice annual Nasal Smear and establishing new QC ranges and standard deviation of assayed controls. Refer to D5401 2) Risk assessment for the Human IgG, IgA & IgM Bindarid Radical Immunodiffusion Kit. Refer to D5445