

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0957235	<b>(X3) Date Survey Completed</b>  03/14/2018
<b>Name of Provider or Supplier</b>  Immunopathogenesis Section	<b>Street Address, City, State</b>  10 Center Drive, Bethesda, MD	
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>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: Based on review of the procedure manual and interview with testing personnel, the laboratory failed to include an evaluation of the environment component as part of it's risk assessment as part of it's Individualized Quality Control Plan (IQCP) used in the Cytokine (Auto-antibody) assay. Findings include: 1. The surveyor reviewed one of one IQCP titled, 'Coupled Bead for Anticytokine Autoantibody Screening' that was developed and approved for use in conjunction with the Cytokine (Auto-antibody) assay as of May 7, 2014. 2. The IQCP Risk Assessment did not cover (or include) an evaluation of the affects of the operating environment (especially, but not limited to: temperature) when writing the Quality Control Plan (QCP) as having provided equivalent quality testing under this seciton. 3. The findings were confirmed by available testing personnel at approximately 1:00pm on the date of the survey.</p>