

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0931212	<b>(X3) Date Survey Completed</b>  01/16/2018
<b>Name of Provider or Supplier</b>  Cytokine Reference Laboratory	<b>Street Address, City, State</b>  13-127 Pwb, 516 Delaware St Se, Minneapolis, MN	
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>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, record review and interview with laboratory personnel, the laboratory failed to include in procedure or perform equipment function checks as defined by the manufacturer . Findings are as follows: 1. A tour of the laboratory on 01/16/18 at 9:10 a.m. revealed the presence of the following laboratory equipment: - Laboratory Research Products, Inc. Refrigerator - Hettich Universal 32 R Centrifuge                      2. Review of equipment maintenance and function check records did not provide evidence that the verification of accuracy for the refrigerator thermometer, or verification of the accuracy for the centrifuge speed and timer, were performed in 2016 and 2017. 3. The Quality Control Manual: Cytokine Reference Laboratory / Section VII Equipment Maintenance procedure, located in the SOP's manual, did not include functional check criteria for verification of accuracy for the refrigerator thermometer, or for the centrifuge speed and timer settings. 4. The laboratory was unable to provide the missing procedural elements upon request. The laboratory was unable to provide the missing function check records upon request. 5. In an interview on 1/16/18 at 11:30 a.m., Technical Supervisors 1 and 2 confirmed the above findings.</p>