

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0077881	<b>(X3) Date Survey Completed</b>  11/29/2018
<b>Name of Provider or Supplier</b>  Newton Wellesley Dermatology Associates Pc	<b>Street Address, City, State</b>  65 Walnut Street Suite 302, Wellesley, MA	
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>D0000</b>	An initial CLIA certification survey was conducted for the Newton Wellesley Dermatology Associates, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on policy review and interview, the laboratory failed to establish a maintenance protocol for the laboratory microscope as evidenced by the following: Procedure review on 11/29/18 revealed no written policies regarding microscope maintenance. There was no documentation that maintenance of the microscope had been performed on a regular basis. The laboratory director confirmed in an interview on 11/29/18 at 1:55 PM that a maintenance schedule had not been set up for the microscope.</p>