

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2101446	(X3) Date Survey Completed 03/27/2018
Name of Provider or Supplier Omni Dermatology, Inc	Street Address, City, State 4515 S Mcclintock Dr Ste 101, Tempe, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<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 review of the laboratory's microscope maintenance policy and interview with the facility personnel, the laboratory failed to indicate the frequency of preventative maintenance of the microscope used in Dermatopathology patient testing. Findings include: 1. The laboratory did not indicate in the microscope procedure policy how often the microscope is undergo preventative maintenance procedures. 2. According to a company sticker on the microscope, an outside company did perform preventative maintenance on the microscope in August 2016 and the microscope was due in August 2017 for preventative maintenance. 3. The facility personnel acknowledged that the maintenance procedures indicated above failed to include specific information regarding the frequency of preventative maintenance activities and that the microscope was not serviced for preventative maintenance in 2017.</p>