

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1093233	(X3) Date Survey Completed 11/27/2018
Name of Provider or Supplier Ab Dermatology	Street Address, City, State 3060 N Arlington Heights Rd, Arlington Heights, IL	
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 the surveyor's review of the laboratory's manuals, logs, direct observations, and an interview with the staff manager; the laboratory failed to follow maintenance and function check protocols that ensures equipment, instrument, and test system performances are accurate and reliable. The laboratory must perform and document the maintenance activities. Findings: 1. On 11/27/2018 at 11:35 AM during a tour of the laboratory, the surveyor observed the following equipment in the laboratory: 1). A Microscope - attached maintenance label records 12/2015 as the last service date. 2). Biological hood (used for tissue staining) - attached maintenance label records 01/07/2016 as the last date the filter was change. 3). A Cryostat; and 4). A Microtome 2. The procedure manual states the following in its "EQUIPMENT MAINTENANCE AND QUALITY CONTROL POLICY: "1. Service technicians will perform required annual maintenance" 3. The service receipts in the maintenance log reveal the following: A). The microscope was last serviced in December of 2015; B). The last filter change for the Biological hood was performed on 01/07/2016; C). The Cryostat was last serviced on 11/30/2017; and D). The Microtome had been serviced on 10/10/2016 and 06/06/2018. No other documentation was provided as evidence the</p>

equipment maintenance had been performed annually as required in the laboratory's equipment policy. 4. On a Recertification survey conducted on 11/27/2018 at 1:15 PM the staff manager confirmed the above findings.