

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0691800	<b>(X3) Date Survey Completed</b>  10/29/2018
<b>Name of Provider or Supplier</b>  Booth Dermatology Group, Pc	<b>Street Address, City, State</b>  12050 N Michigan Rd, Zionsville, IN	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: The Standard is not met as evidenced by: Based on observation, document review, and interview, the laboratory failed to document compliance with manufacturer's maintenance requirements for one of one cryostat (Avantik Cryostat, serial #51722) in use during 2018, for one of twelve patients (P-8) reviewed in the subspecialty of Histopathology. Findings include: 1) On 10/20/18 at 12:30 PM, during tour an AVANTI K Cryostat, serial #51722, was in operation. 2) Review of AVANTI K "EQUIPMENT QUALITY CONTROL---CRYOSTAT", no approval date, indicated the following maintenance procedures were required: a) defrost of machine daily; b) change of cryostat blade at least every 20th case; c) clean condenser coils; d) annual change of air filter; e) weekly oil of flywheel and components; f) document problems with cryostat; g) deep cleaning every six months. 3) Review of laboratory log "Maintenance Record---Cryostat", indicated the above maintenance was not completed on the following dates: a) January 2018 to June 2018, a, b, c, d, f, and g, were not documented; and, e was not documented on March 29 and May 3. b) July 2018 to October 2018, a, b, c, d, f, and g were not documented; and, e was not documented July 12, August 23, September 13, and October 4. 4) Review of test report for patient P-8 testing date (05-10-18), indicated six of nine (a, b, c, d, f, and g) maintenance steps were not documented for the cryostat, when patient P-8 was tested (1404 histopathology tests performed annually). 5) In interview on 10/29/18 at 2:30 PM, SP-1 indicated the following: a) cryostat is defrosted as needed, but not documented; b) the cryostat blade is changed daily, if not more on Mohs surgical procedure days, but not documented; c) the flywheel and moving parts are oiled</p>

weekly, but not always documented; d) issues with the cryostat are corrected, but not documented; and, e) the lab has maintenance on the cryostat yearly, but could not provide documentation for the detail of work done. 6) In interview on 10/29/18 at 2:36 PM, SP-2 indicated the following: a) condenser coils are cleaned after each Mohs, but not documented; b) the air filter of the fume hood is changed at the annual inspection (could not provide detail of service); and, c) deep cleaning is performed every six months, but not documented.