

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0209146	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier Braun Dermatology	Street Address, City, State 3301 New Mexico Avenue Nw, Suite 301, Washington, DC	
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
D5435	<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:</p> <p>A. Based on review of the written procedure manual and interview with the laboratory person, the laboratory failed to establish maintenance procedures for the autoclave to ensure accurate and reliable patient testing. Findings: 1. The laboratory has an autoclave where instruments used for patient procedures are sterilized. 2. The laboratory did not have written procedures nor documentation that showed the autoclave was checked for spore contamination. 3. The laboratory person stated that he was unsure if the autoclave was ever checked for spore contamination. 4. The laboratory person confirmed that written maintenance procedures were not available to ensure that contamination procedures were performed on the autoclave. B. Based on review of the written procedure manual and interview with the laboratory person, the laboratory failed to document all maintenance procedures performed on the cryostat. Findings: 1. The laboratory written cryostat maintenance procedure states "after each frozen section is completed the blade is cleaned, moved to a new position, or replaced. 2. The laboratory did not document when the cryostat blade was replaced.</p>

3. The laboratory person stated that there was no need to document this because the person performing the cutting should know when to change the blade. 4. The testing person confirmed that the cryostat blade changes were not documented.