

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0924251	(X3) Date Survey Completed 03/10/2021
Name of Provider or Supplier Advanced Dermatology And Skin Cancer Center	Street Address, City, State 2735 Pembroke Place, Manhattan, KS	
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: Based on an absence of service records and interview, the laboratory failed to perform a function check protocol for the cryostats, tissue processor and ventilation hood. Findings: 1. No documentation was available for function checks on 2 of 2 cryostats (Leica CM1950 models) for the year 2020. 2. No documentation was available for function checks for the tissue processor (Leica ASP 3005) for the years 2019 and 2020.. 3. No documentation was available for function checks for the ventilation hood (Labconco) for the years 2019 and 2020.. 4. Interview with the Testing Personnel #2 on March 10, 2021 at 11:15 a.m. confirmed, the laboratory failed to perform a function check protocol for the cryostats, tissue processor and ventilation hood.</p>