

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2207992	(X3) Date Survey Completed 07/21/2021
Name of Provider or Supplier Resolute Dermatology Llc	Street Address, City, State 6800 Hilltop Rd Ste 102, Shawnee, 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 thermometer function check records or certificates of accuracy, protocols for thermometer and hygrometer function checks and interview, the laboratory failed to define and perform a function check protocol for 2 of 2 thermometers and 1 hygrometer. Findings: 1. No documentation was available for function checks on 2 of 2 thermometers and 1 of 1 hygrometers at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on 2 of 2 thermometers and 1 of 1 hygrometers at the time of survey. 3. Proctocols for the function checks of thermometers and hygrometer were not made available at the time of survey. 4. Interview with the laboratory director on 7/21/2021 at 2:45 p.m. confirmed, the laboratory failed to define and perform a function check protocol for 2 of 2 thermometers and 1 hygrometer.</p>