

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0974166	(X3) Date Survey Completed 08/27/2024
Name of Provider or Supplier Macaione & Papa Dermatology Assoc	Street Address, City, State 707 White Horse Road, Voorhees, NJ	
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 surveyor review of the Therm Pro thermohygrometer used for room temperature and humidity in the laboratory and interview with the Laboratory Director (LD), the laboratory failed to provide documentation of calibration for the Therm Pro thermohygrometer used in the laboratory from 6/6/23 to 8/27/24. The findings include: 1. The laboratory could not provide documentation of calibration for the Therm Pro thermohygrometer used for room temperature and humidity. 2. The LD confirmed on 8/27/24 at 10:00 am that they could not provide documentation of calibration for the Therm Pro thermohygrometer.</p>