

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0225155	<b>(X3) Date Survey Completed</b> 10/17/2019
<b>Name of Provider or Supplier</b> Dermatology Associates Inc	<b>Street Address, City, State</b> 1514 Amherst Street, Winchester, VA	
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>D0000</b>	An announced CLIA recertification survey was conducted at Dermatology Associates Inc on October 17, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's guidelines, lack of daily temperature /relative humidity (RH%) documentation, and interviews, the laboratory failed to ensure manufacturer's environmental operating requirements were followed for the Advantik QS12 Cryostat during the twenty (20) of 20 months reviewed from March 2018 until the date of the survey on October 17, 2019. Findings include: 1. During a tour of the laboratory at approximately 9:30 AM, the surveyor noted an Advantik QS 12 Cryostat in use for preparing MOHS specimens for patient testing. 2. Review of the "Advantik QS12 Cryostat Instruction Manual" for environmental operating requirements revealed the following requirements for the QS12 Cryostat: "Temperature (Operating Limits) +5C to +35C (+41F to +95F)" "Relative Humidify Max. 60% RH up to 35C)" 3. Review of the laboratory's records revealed a lack of documentation of the daily temperature and RH% from March 2018 until the date of the survey on October 17, 2019. The surveyor requested to review the daily</p>

temperature and RH% from March 2018 until October 2019. The laboratory provided no document for review. The MOHS technician stated that he/she monitors the temperature and relative humidity but does not have documentation. 4. In an exit interview with the practice manager and patient advocate at approximately 1:00 PM, the above findings were confirmed.