

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1007699	(X3) Date Survey Completed 08/24/2021
Name of Provider or Supplier American Skin And Cancer Center	Street Address, City, State 95 First Avenue, Atlantic Highlands, 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
D5413	<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 surveyor review of the Temperature Records (TR) and interview with the Office Manager (OM), the laboratory failed to document Room Temperature (RT) where Histopathology test reagents were stored and tests were performed from 1/5/19 to the date of the survey. The findings include: 1. There were no temperatures recorded. 2. The OM confirmed on 8/24/21 at 12:45 pm that the laboratory failed to accurately record RT.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of maintenance records and interview with the Office Manager (OM), the laboratory failed to perform and document annual maintenance on the microscope</p>

used in laboratory testing from 1/5/19 to the date of the survey. The OM confirmed on 8/24/21 at 12:30 pm there was no documented evidence that annual maintenance was performed on the microscope from January 2019 to the date of the survey.