

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1007699	(X3) Date Survey Completed 01/24/2024
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Biannual Assessment Records (BAR) and interview with the Office Manager (OM) the laboratory failed to verify the accuracy of Histopathology testing from 8/24/21 to the date of survey. The findings include; 1. The reviewing physician stated in the PM was not the reviewing physician on the BAR for calendar years 2022 and 2023. 2. There was no documented evidence the referring physician reviewed the results of the BAR upon completion for calendar years 2022 and 2023. 5) The OM confirmed on 1/24/24 at 11:30 am that the laboratory failed to verify the accuracy of Histopathology testing.</p>
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:</p>

Based on the lack of Temperature Logs (TL), review of the Users Manual (UM) for the Olympus CX43 microscope and interview with the Office Manager (OM), the laboratory failed to monitor and document room temperature and humidity where the Professional component (PC) for Histopathology tests are performed from 8/4/21 to the date of the survey. The findings include: 1. The UM defined the operating environment ambient temperature as 5 to 40C (41 to 104 F). 2. The UM defined the operating environment maximum as 80%. 3. There was no record of temperature or humidity in the office where the PC was being performed. 4. The OM confirmed on 1/24/24 at 11:35 am the laboratory failed to monitor and document room temperature and humidity.