

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1080362	(X3) Date Survey Completed 01/29/2024
Name of Provider or Supplier Advanced Dermatology Assoc Ltd	Street Address, City, State 236 Brodhead Rd, Suite #100, Bethlehem, PA	
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 observation of the laboratory, lack of documentation, and interview with Testing Personnel (TP) #13, the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met in the histopathology laboratory from 06/22/2022 to the day of survey. Findings Include: 1. On the day of survey, 01/29/2024 at 10:58 am, during the laboratory tour, the surveyor discovered room temperature and humidity was not monitored in the laboratory where the cryostat was located from 06/22/2022 to the day of survey. 2. According to manufacturer's instructions, operating conditions for the Avantik cryostat are from +5C up to +35C and at a maximum relative humidity of 60%. 3. The laboratory was not able to provide room temperature or humidity records for the laboratory from 06/22/2022 to 01/29/2024. 4. The laboratory's annual volume for Histopathology is 205. (CMS-116) 5. Interview with TP #13 on 01/29/2024 at 11:30 am confirmed the findings above.</p>