

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0969601	<b>(X3) Date Survey Completed</b>  12/05/2019
<b>Name of Provider or Supplier</b>  Advanced Dermatology Of Michigan	<b>Street Address, City, State</b>  4170 Cedar Bluff Drive, Petoskey, MI	
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>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 observation, record review, and interview with the moha technician, the laboratory failed to document cryostat operating temperatures for 2 (December 2017 to December 2019) of 2 years. Findings include: 1. An observation on 12/5/19 at 8:05 am by the surveyor revealed the laboratory had a Leica CM 1850 cryostat in use. 2. A review of the laboratory's established "General Laboratory Quality Assurance" policy revealed a section stating, "Temperatures are taken and recorded in the Histology Laboratory each day of operation. Cryostat, refrigerator, freezer and room temperature are taken in the morning and recorded on the appropriate temperature recording form." 3. A review of laboratory temperature records revealed a lack of recorded cryostat operating temperatures. 4. An interview on 12/5/19 at 9:15 am with the moha technician confirmed the laboratory had not been recording cryostat operating temperatures.</p>