

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0690144	<b>(X3) Date Survey Completed</b>  09/13/2021
<b>Name of Provider or Supplier</b>  Advanced Dermatology Of Michigan	<b>Street Address, City, State</b>  6100 Newport Rd, Suite 100, Portage, 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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Office Manager, the laboratory failed to ensure reagents were labeled with the expiration date for 1 bottle of 100% alcohol observed. Findings include: 1. During a tour of the laboratory on 9/13/21 at 12:07 pm, the surveyor observed a small plastic bottle with a "100% Alcohol" label. The bottle did not contain the expiration date of the reagent. 2. A review of the laboratory's "Histopathology for Mohs Micrographic Surgery" procedure revealed a section titled "Reagent Labeling" stating, "The manufacturer labels commercially prepared reagents. All containers used in the staining process must contain the name of the reagent as well as the lot number and expiration date. Dilutions or transfers of volatile materials will be performed under a ventilated hood. Original labels must include name of reagent, warning if reagent is hazardous, expiration date, strength, concentration, or dilution of reagent, preparation date and storage requirements" 3. An interview on 9/13/21 at 12:12 pm with the Office Manager confirmed the bottle did not have an expiration date.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

. Based on observation and interview with the Office Manager, the laboratory failed to ensure tissue marking dyes used in tissue specimen grossing were not expired for 4 of 7 tissue marking dyes observed. Findings include: 1. During a tour of the laboratory on 9/13/21 at 12:07 pm, the surveyor observed 4 expired tissue marking dyes with the expiration date of 2/1/21. 2. An interview on 9/13/21 at 12:11 am with the Office Manager confirmed the tissue marking dyes used were expired.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager, the Laboratory Director failed to approve the procedure manual of the laboratory's testing process for 7 (March 2021 to September 2021) of 7 months since the current Laboratory Director was instated. Findings include: 1. A review of the laboratory's procedure manual revealed a lack of documentation of the Laboratory Director approving the laboratory's testing procedures. 2. An interview on 9/13/21 at 12:44 pm with the Office Manager confirmed the current Laboratory Director had not approved the laboratory's testing procedures since becoming the Laboratory Director on 2/26/21.