

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2088282	<b>(X3) Date Survey Completed</b>  09/11/2024
<b>Name of Provider or Supplier</b>  New Dermatology Group Ltd	<b>Street Address, City, State</b>  2500 E Capitol Dr, 3rd Floor, Appleton, WI	
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 surveyor observation of supplies in the laboratory and interview with Testing Personnel (Staff A), the laboratory did not ensure the label on one of one dispensing bottle of mounting medium indicated the contents of the bottle. Findings include: 1. Observation of supplies in the laboratory revealed a dispensing bottle labeled Clearium with an expiration date of October 20, 2022. Further observation revealed one opened bottle of Micromount mounting medium and one unopened bottle of Micromount mounting medium. 2. Interview with Staff A on September 11, 2024, at 9:45 AM confirmed the dispensing bottle contained Micromount mounting medium and confirmed the label on the dispensing bottle did not accurately indicate the contents of the bottle.</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 deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor observation of testing supplies and interview with Testing Personnel (Staff A), the laboratory used expired Micromount mounting medium, two of two bottles expired on December 22, 2023. Findings include: 1. Observation of supplies in the laboratory showed two bottles of Micromount mounting medium, one partially used, the second unopened. Both showed lot number 122221 with an expiration date of December 22, 2023 (2023-12-22). 2. Interview with Staff A on September 11, 2024, at 9:45 AM confirmed the Micromount mounting medium had expired on December 22, 2023, and confirmed the laboratory used the Micromount mounting medium after the expiration date.