

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D2014645	<b>(X3) Date Survey Completed</b> 12/10/2024
<b>Name of Provider or Supplier</b> University Dermatology Associates	<b>Street Address, City, State</b> 400 Red Creek Drive, Suite 200, Rochester, NY	
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>D0000</b>	An announced CLIA exempt-state validation survey was conducted at UNIVERSITY DERMATOLOGY ASSOCIATES on December 10, 2024, by a federal surveyor from the CMS CLIA Survey Branch. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to be compliance with condition-level CLIA requirements but not standard-level CLIA requirements. The following standard-level deficiency was found during the CLIA exempt-state validation survey performed on December 10, 2024.
<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: Based on observation of the laboratory and interview with the Histotechnologist (HT), the laboratory failed to discard three of three bottles of tissue marking dyes that had expired in 2023 and 2024. Findings Include: 1. Observation of the laboratory on December 10, 2024 at 8:20 am, revealed 3 of 3 bottles of tissue marking dyes that had expired on the following dates below: a. Mercedes Scientific - one of one 8 oz bottle - Red - Lot#21306 - expired 11/30/2023. b. Avantic Bio Group - one of one 2 oz bottle - Violet - Lot#159586 - expired 10/31/2024. c. Avantic Bio Group - one of one 2 oz bottle - Red - Lot#154468 - expired 08/31/2024. 2. A total estimated 1,881 tests are performed annually for histopathology. 3. The HT confirmed the findings above on December 10, 2024, at 8:30 am</p>