

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2256391	(X3) Date Survey Completed 05/08/2024
Name of Provider or Supplier Hudson Dermatology, Pc	Street Address, City, State 98 Green Street, Suite 4, Hudson, NY	
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
D5417	<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 direct observations and interview with the Practice Manager (PM), the laboratory failed to remove from inventory expired reagents in the Mohs processing laboratory as required by the Hudson Dermatology Quality Control Manual standard operating procedure. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on May 8, 2024, at approximately 9:30 A.M. the following reagents and processing materials were not removed from inventory as required by the Hudson Dermatology Quality Control Manual standard operating procedure: a. StatLab Acrymount Mounting Media lot: 0276 expiration: October 22, 2022; and lot: 6159 expiration: June 7, 2028, were stored in an overhead cabinet in the Mohs processing laboratory. b. Mercedes Scientific OpticMount 1 Toluene lot: 44947 expiration: January 31, 2024, was stored in an overhead cabinet in the Mohs processing laboratory. c. Sakura Tissue-Tek O.C.T Compound lot: 2582-00 expiration: August 31, 2023, was stored in an overhead cabinet in the Mohs processing laboratory. d. Polarstat Plus Frozen Embedding Medium lot: 108749 expiration: September 30, 2022, was stored in an overhead cabinet in the Mohs processing laboratory. e. Avantik Tissue Marking Dyes lot: 051786 expiration: February 2019; lot: 051510 expiration: December 2018; and lot: 051260 expiration: October 2018 were stored in an overhead cabinet in the Mohs processing laboratory. f. It was noted that the respective reagents and processing materials were removed from the Mohs processing laboratory inventory during the survey in partial satisfaction of</p>

this requirement. 2. The PM confirmed on May 8, 2024, at approximately 10:00 A.M. that the respective expired reagents and processing materials were not utilized for patient specimen processing.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the Hudson Dermatology Mohs Log Worksheets and interview with the PM, the laboratory failed to comply with instructions indicated in the current, approved Hudson Dermatology CLIA Manual Daily Logging/Recording Policy #4 standard operating procedure. FINDINGS: 1. The laboratory failed to document "Cryostat Make/Model", "Cleaned with 100% Alcohol", and "Technician's Signature and Date" on the May 7, 2022, July 16, 2022, January 7, 2023, March 11, 2023, and May 20, 2023, Hudson Dermatology Mohs Log Worksheets. 2. This was contrary to instructions indicated in Hudson Dermatology CLIA Manual Daily Logging /Recording Policy #4 standard operating procedure. 3. The PM confirmed the findings on May 8, 2024, at approximately 10:45 A.M. 4. It was noted that the respective documentation was completed during the survey in partial satisfaction of this requirement.