

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2244940	(X3) Date Survey Completed 08/16/2023
Name of Provider or Supplier Dolehide Dermatology At Silver Cross	Street Address, City, State 1851 Silver Cross Blvd - Ste 150, New Lenox, IL	
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 the surveyor's review of laboratory records, direct observation, and an interview with testing personnel (TP 2), the laboratory failed to ensure three of three tissue marking dyes were not used for histopathology testing after exceeding their expiration dates. Affecting two of two testing months (07/2023 and 08/2023). Findings Include: 1. Review of the "Mohs Laboratory Reagent Protocol" revealed the following: a. "PURPOSE: As part of the Mohs laboratory's quality control, the shelf-life of laboratory reagents is recorded upon receipt and monitored monthly. Expired reagents are identified and properly disposed." b. "PROCEDURES: 2. Each month the lab supplies and reagents are checked for expiration dates. 3. If the supplies or reagents are found to have become outdated, they are disposed of according to the recommended disposal method on the MSDS sheet for that reagent." 2. On 08/16/2023 at 11:25 a.m., the surveyor's direct observation revealed exceeded expiration dates for three of three tissue marking dye reagents. a. "ReOrder #GR2056-GN (11-9005-12) - EXP: 2023-07-31" b. "ReOrder #GR2056-GN (11-9005-12) - EXP: 2023-07-31" c. "ReOrder #GR2056-R (11-9002-12) - EXP: 2023-06-30" 3. On 08/16/2023 at 11:30 a.m., TP 2 confirmed the above findings.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the manufacturer's maintenance schedule, laboratory records, lack of documentation, and an interview with testing personnel (TP 2), the laboratory failed to perform and document the maintenance for one of one biosafety cabinets for two of two testing years (2022 and 2023). Affecting a total of 207 Mohs surgeries. Findings Include: 1. Review of the laboratory's "Quality Control Policy" revealed the following: a. "Quality Control: Equipment Maintenance and Records 4.b. - Staff will perform and document the required routine and daily maintenance on instruments and equipment. 7. The laboratory must maintain documentation of daily function checks and/or maintenance checks for the preceding 2 years." 2. Review of the manufacturer's "Purair Basic Consumable Parts List" for one of one biosafety cabinets (Air Science biosafety cabinet - Serial # P7573) revealed the following: a. "Replace Pre-filters every 2 - 3 Months" b. "Replace Main Filter Every 12 Months" 3. Review of laboratory records and lack of documentation revealed the laboratory failed to perform and document the maintenance for one of one biosafety cabinets (Air Science biosafety cabinet - Serial # P75733) for two of two testing years (2022 and 2023). Affecting a total of 207 Mohs surgeries. 4. On 08 /16/2023, at 10:30 a.m., TP 2 confirmed the above findings.