

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2111512	(X3) Date Survey Completed 12/16/2024
Name of Provider or Supplier True Dermatology	Street Address, City, State 615 1st North, Alabaster, AL	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2023 Room Temperature (RT) and Humidity logs of the laboratory, and an interview with Laboratory Director (LD), the staff failed to document the RT and Humidity each day of patient testing. The surveyor noted there were no RT recorded for 3 out of 30 days in June 2023, and no Humidity was recorded for 1 out of 30 days in June 2023. The laboratory performed 48 Mohs patient procedures on those days. The findings include: 1) A review of the 2023 RT and Humidity logs revealed the staff did not monitor and document the RT and Humidity when MOH's patient procedures were performed for the following days: A) No RT documented on June 19, 2023, with 16 Mohs procedures performed. B) No RT documented on June 26, 2023, with 14 Mohs procedures performed. C) No RT documented on November 27, 2023, with 18 Mohs procedures performed. D) No Humidity documented on June 19, 2023, with 16 Mohs procedures performed. 2) LD confirmed the findings during the exit conference on 12-16-2024 at 12:55 PM.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a direct observation review of the laboratory and an interview with the Laboratory Director (LD) and the Testing Personnel, the laboratory utilized expired materials for the Mohs patient slide preparation procedures. This was noted for the expiration dates on the material containers to the current date of the survey. The findings include: 1. During the laboratory tour on 12-16-2024 at approximately 8:15 AM, the surveyor observed the following expired materials were utilized for the Mohs patient slide preparation procedures: (A) Mercedes Scientific Subzero Tissue Freezing Medium, Lot number 131449 with expiration of 3-31-2023, (B) Mercedes Scientific LiquiMount Mounting Medium, Lot number 148199 with expiration date of 3-31-2024. 2. A further review of the material containers revealed no open dates were written on the containers. 3. The LD confirmed these findings during the exit conference on 12-16-2024 at 12:55 PM.