Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2030690	11/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Montrose Dermatology	2730 Commercial Way, Montrose, CO	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on records review and an interview with the Practice Manager (not included on CMS-209 form), the laboratory failed in 2022 and 2023 to perform twice annual verification testing for: Mohs histopathology slide interpretation, Potassium Hydroxide (KOH) preparations and Scabies testing. The laboratory performs approximately 555 Mohs histopathology procedures, approximately 11 KOH preparations, and approximately 11 Scabies procedures per year. Findings include: 1. Records review revealed that the laboratory failed to perform twice annual accuracy verification for Mohs histopathology slide interpretation, Potassium Hydroxide (KOH) preparations, and Scabies procedures for years 2022 and 2023. 2. An interview with the Practice Manager (not included on CMS-209 form) at approximately 2:30 PM on November 14, 2023, confirmed that the laboratory failed to perform twice annual accuracy verification for Mohs histopathology slide interpretation, Potassium Hydroxide (KOH) preparations, and Scabies procedures for years 2022 and 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on a record review, and interview with the Practice Manager (not included on CMS-209 form), the laboratory failed to establish acceptable environmental conditions such as monitoring and documenting the temperature, and relative humidity (RH) of the Mohs laboratory space and the Leica cryostat histopathology processing instrument for 2023. The laboratory performs approximately 555 Mohs histopathology procedures per year. Findings include: 1. A record review revealed that the laboratory failed to establish and document acceptable temperature ranges for the Mohs laboratory space, or the laboratory's Leica cryostat histopathology processing instrument in the year of 2023. 2. A record review revealed the laboratory failed to establish and document acceptable relative humidity (RH) ranges for the Mohs laboratory space for the year of 2023. 3. An interview with the Practice Manager (not included on CMS-209 form), at approximately 2:45 PM, confirmed that the laboratory failed to establish and document the temperature and RH of the Mohs laboratory space, and establish and document the temperature of the laboratory's Leica cryostat histopathology processing instrument.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Practice Manager (not include on CMS-209 form), the laboratory failed to use reagents that had not exceeded their expiration dates for six out of six Tissue Marking Dyes. The Laboratory performed approximately 60 Mohs procedures since the reagents had expired. Findings include: 1. An observation of the laboratory's reagents and stains at approximately 2:00 PM, revealed six bottles of Tissue Marking Dyes had exceeded their expiration dates. A) Color black, expiration date: 03/31/2023. B) Color green, expiration date:02/28/2023. C) Color red, expiration date:12/31/2022. D) Color blue, expiration date:02/28/2023. E) Color yellow, expiration date: 04/30/2023. F) Color orange, expiration date: 02/28 /2023 2. An interview with the Practice Manager (not included on CMS-209 form) at approximately 2:45 PM, confirmed that the six Tissue Marking Dyes had expired and had been used for the inking process for approximately 60 Mohs specimens.