Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2198255	06/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Dermatology And Vein	14008 Shadow Glen Blvd Ste 200, Manor, TX	

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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, slides, and interview, the laboratory failed to label the slides with the patient's name on one of ten cases reviewed in dermatopathology. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance, approved 01/05/2022, under 5.3 Frozen Sections stated, "The assigned frozen accession number, patient name, date of procedure and tech initials will be labeled on the slide." B. Review of a combination of ten Mohs and Frozen section biopsy cases showed the Frozen Section biopsy case GMF23-002 did not have the patient's name on the slide. C. Interview with the Laboratory Director on June 14, 2023 at 1045 confirmed the findings and added GMF23-001 from the same patient was also not labeled with the name.
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: I. Based on review of manufacturer's instructions, laboratory's policy and procedure, temperature logs, testing logs, pre-survey paperwork, and interview, the laboratory failed to ensure the temperature was within the operating specifications for the Avantik QS12 cryostat used in Mohs testing for 12 of 12 months reviewed over 16 days of testing. Findings follow. A. Review of the Avantik QS12 Instruction Manual, 5259000 rev 1, on chapter 2. Introduction under Technical Specifications stated, "Temperature (Recommended Operation) 15 to 30 degrees Celsius (59 to 86 degrees Fahrenheit) Note Performance may deteriorate when operated outside of this range". B. Review of the laboratory's policy and procedure titled Equipment Management, approved 01/05/2022, at 5.0 Procedure stated, "The temperature and humidity is checked and recorded each day for all temperature dependent equipment and environments using a thermometer." C. Temperature logs were requested on June 14, 2023 at 1015 hours but not provided. D. Review of the Mohs Accession Logs from 06 /08/22 - 06/05/23 showed Mohs testing was performed on the following dates: 06/05 /23, 05/11/23, 04/03/23, 03/06/23, 02/06/23, 01/09/23, 12/05/22, 11/07/22, 10/12/22, 09/14/22, 08/31/22, 08/17/22, 08/03/22, 07/20/22, 07/06/22, and 06/08/22. E. Interview with the Laboratory Director on June 14, 2023 at 1015 hours confirmed the laboratory did not monitor room temperature. F. Review of the CMS form 116 showed approximately 171 stages were performed annually. II. Based on review of manufacturer's instructions, laboratory's policy and procedure, humidity logs, testing logs, pre-survey paperwork, and interview, the laboratory failed to ensure the humidity was within the operating specifications for the Avantik QS12 cryostat used in Mohs testing for 12 of 12 months reviewed over 16 days of testing. Findings follow. A. Review of the Avantik QS12 Instruction Manual, 5259000 rev 1, on chapter 2. Introduction under Technical Specifications stated, "Relative Humidity [RH] maximum 60% RH up to 35 degrees Celsius". B. Review of the laboratory's policy and procedure titled Equipment Management, approved 01/05/2022, at 5.0 Procedure stated, "The temperature and humidity is checked and recorded each day for all temperature dependent equipment and environments using a thermometer." C. Humidity logs were requested on June 14, 2023 at 1015 hours but not provided. D. Review of the Mohs Accession Logs from 06/08/22 - 06/05/23 showed Mohs testing was performed on the following dates: 06/05/23, 05/11/23, 04/03/23, 03/06/23, 02/06 /23, 01/09/23, 12/05/22, 11/07/22, 10/12/22, 09/14/22, 08/31/22, 08/17/22, 08/03/22, 07/20/22, 07/06/22, and 06/08/22. E. Interview with the Laboratory Director on June 14, 2023 at 1015 hours confirmed the laboratory did not monitor humidity. F. Review of the CMS form 116 showed approximately 171 stages were performed annually.
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 observation, review of manufacturer's instructions, pre-survey paperwork, and interview, the laboratory failed to ensure reagents were not used beyond their expiration for seven of seven tissue marking dyes, two of two submount mounting media, 16 of 16 bottles of frozen embedding medium, and four of four bottles of frozen section compound currently in use by the laboratory used in Mohs testing. Findings follow. A. Expired Supplies: 1. Surveyor observed on June 14, 2023 at 1020 hours in the laboratory seven of seven Stat Lab Tissue Marking Dyes available and in use by the laboratory were expired as listed by color, Lot number, and expiration date: a. Red 104899 08/31/22 b. Blue 105571 09/30/22 c. Orange 104908 08/31/22 d. Green 104169 08/31/22 e. Yellow 105567 09/30/22 f. Violet 102900 07/31/22 g. Black 103254 07/31/22 2. Surveyor observed on June 14, 2023 at 1025 hours in the laboratory two of two bottles of Submount Mounting Media, Lot 1145, expiration 05 /25/22 available and in use by the laboratory. 3. Surveyor observed on June 14, 2023 at 1030 hours in the laboratory 16 of 16 bottles of Stat Lab Polarstat Plus Frozen Embedding Medium, Lot 118027, expiration 03/31/2023 available and in use by the laboratory. 4. Surveyor observed on June 14, 2023 at 1030 hours in the laboratory four of four bottles of Ultra Freeze Frozen Section Compound, Lot 20324, expiration 11/22 available and in use by the laboratory. B. Interview with the Laboratory Director on June 14, 2023 at 1015 and 1035 hours confirmed the findings. C. Review of the CMS form 116 showed approximately 171 stages were performed annually.