Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2015671	11/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Md, Pa	804 Ne Mall Blvd, Hurst, 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 found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 laboratory policy, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least two unique patient identifiers for 16 of 16 slides in 2023 (random review) and 19 of 19 slides in 2024 (random review). Findings included: 1. Review of the laboratory policy manual section page 7 revealed: "D. Labeling of Frozen Section Slides Purpose: To provide a standard for labeling of slides Slides are to be labeled before frozen sections are cut a. Information to be written with a slide marking pen on the frosted end of the slide. b. Line 1 - Surgery Accession (Case) # c. Line 2- Patient last name and first initial d. Line 3 - Stage# (Stage 1 is implied and is not noted on the slide)/lesion designation (A, B, etc.), Tissue Piece# e. A second or third slide on the same piece of tissue is noted with A, B, or Caswell f. Slides are to be labeled IA S 1, IA S2 g. If for some reason the same number is assigned by accident, an X will be placed on the re-used # to identify that it has been used over accidently on the slides." An example of how to label a slide was illustrated in the policy: " SMD(yr)-# Doe, J. IA S1" The laboratory policy did NOT include labeling instructions to reliably identify patients using at least two unique patient identifiers to distinguish between

	specimens. 2. A random review of patient slides from 2023 and 2024 revealed the following: 2023 11 slides labeled with a patient Mohs accession number, last name and first initial, stage number and piece number. The Mohs accession numbers were as follows: SMD23-050, SMD23-052, SMD23-053, SMD23-054, SMD23-055 5 slides labeled with a patient Mohs accession number, stage number and piece number. The Mohs accession numbers were as follows: SMD23-050, SMD23-052, SMD23-053, SMD23-054, SMD23-055 2024 17 slides labeled with a patient Mohs accession number, last name and first initial, stage number and piece number. The Mohs accession numbers were as follows: SMD24-043, SMD24-055, SMD24-056, SMD24-057, SMD24-058 2 slides labeled with a patient Mohs accession number, stage number and piece number. The Mohs accession numbers were as follows: SMD24-043, SMD24-058 The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least two unique patient identifiers. 3. During an interview on 11 /22/2024 at 10:10 a.m., the Practice Manager after a review of the records, confirmed the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least two unique patient identifiers.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory maintenance logs, and confirmed by staff interview, the laboratory failed to have documentation of performing daily maintenance for the microscope, cryostat and countertop for four of seven days in 2024 (July, August, September, November). Findings included: 1. Review of the laboratory's policy manual pages 14 and 15 stated: "D. Cryostat Care Purpose: To maintain a clean safe cryostat interior and to monitor cryostat functions. Surgery Days: Wear gloves and surgical scrubs. Do not tum off cryostat unless defrosting. 1. Remove disposable blade from the holder and discard in sharps box or used blade section of the blade dispenser. If the blade is still usable, place it in the back-up cryostat for safety. 2. Remove blade holder and place in the back-up cryostat. 3. All other loose and removable items are to be removed from the cryostat and placed on a towel on the counter to be wiped with95% [sic] alcohol. 4. Using brushes, remove as much loose OCT/tissue debris as possible. 5. With gauze saturated with 95% alcohol, wipe all interior surfaces that can be reached. Use clean gauze as needed. Wipe with dry gauze. 6. Replace items in proper places in cryostat. 7. Wipe glass fly wheel and outside of cryostat with 95% alcohol. Change paper towels and other top items as needed. * Defrosting (done when surgeon is out of town so there is plenty time for all freezing coils and moving parts to dry before turning it back on. If not sufficiently dry, it is not operable due to "freeze up.") Tum [sic] cryostat off and unplug. Follow procedure above. Also remove the microtome for cleaning. Plug back in, tum [sic] on, and reset temperature/clock if necessary. A log will be maintained including the following: 1. Documenting the temperature of the cryostat monthly. 2. Defrost cryostat (as needed for ice build-up) 3. Preventative maintenance by service

	professional when needed. E. Microscope Care Purpose: To maintain a clean safe Microscope exterior and to maintain the focus and calibration. Procedure: Call Sherwood to re-calibrate whenever the microscope is moved or if any difficulty is noted. In the case of microscope malfunction, a back-up microscope is available at the other office location and can be brought by an employee to the location needed. The following maintenance will be provided for the microscope located in the MOHS lab: 1) Monthly Maintenance A. Visually inspect microscope. B. Ensure proper function of light and optics. C. Turn off microscope at the end of the day. D. If any malfunction is noted, this must be reported to the Laboratory Director. E. Clean oculars and stage and lens with lens cleaning tissue every week. F. Wipe down microscope with alcohol wipe." 2. Review of the laboratory's maintenance log stated: "CLEANING LOG" "LOG SURGERY DAYS ONLY" Tasks to be completed were cleaning of the microscope, cryostat and countertop. Further review of the maintenance log for 2024 revealed the following four of seven surgery dates maintenance was NOT documented: 07/13/2024 08/10/2024 09/07/2024 11/09/2024 On 11/22/2024 at 10:10 a.m., the laboratory was asked to provide documentation for the missing dates, and none was provided. 3. During an interview on 11/22/2024 at 10: 20 a.m., the Practice Manager after a review of the records, confirmed the laboratory failed to have documentation of performing daily maintenance for the microscope, cryostat and countertop in 2024.