Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2206671	07/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Scottsdale Skin Boutique And Dermatology	11333 N Scottsdale Rd, Suite 115, Scottsdale, AZ	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual for Mohs and interview with the laboratory director (LD), the procedure manual failed to include the laboratory's system for entering results in the patient record and reporting patient results. Findings include: 1. The laboratory performs the microscopic interpretation of patient slides in conjunction with the Mohs procedure under the subspecialty of Histopathology. Patient testing began on April 20, 2021, with a reported annual test volume of 340. It is the practice of the laboratory to enter the Mohs test results into the patient's Electronic Health Record (EHR). 2. The Mohs procedure manual reviewed during the

	survey failed to include the laboratory's system for entering and reporting results in the patient's' EHR. 3. Interview with the LD on July 10, 2023 at 1:35 PM confirmed the Mohs procedure manual lacked information regarding the laboratory's system for entering and reporting patient test results in the EHR.
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 lack of temperature records for review and interview with the laboratory director (LD), the laboratory failed to monitor and document the room temperature and humidity of the area where dermatopathology stain reagents and testing equipment are stored and utilized, and failed to monitor and document the temperature of the cryostat used in conjunction with Mohs testing. Findings include: 1. Review of the laboratory's room temperature log from 2023 showed an acceptable room temperature range of 60 to 80 degrees Fahrenheit (F) and an acceptable humidity range of less than 60% for the area where dermatopathology stain reagents are stored and the cryostat is used for processing patient specimens. 2. The laboratory failed to monitor and document the room temperature and humidity measurement of the area indicated above on March 29, 2023. Two patients were tested on that date. 3. Review of the laboratory's cryostat temperature log from 2023 showed an acceptable temperature range of -21 degrees Celsius (C) to -30 degrees C. 4. The laboratory failed to monitor and document the cryostat temperature on March 29, 2023. Two patients were tested on that date. 5. The LD interviewed on July 10, 2023 at 1:54 PM confirmed the laboratory failed to monitor and document the cryostat temperature, and room temperature and humidity of the area where reagents are stored and used for patient testing as indicated above.
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 the laboratory's microscope maintenance policy and interview with the laboratory director (LD), the laboratory failed to perform and document the annual preventative maintenance of the microscope used for patient testing under the

	subspecialty of Histopathology. Findings include: 1. The laboratory's established microscope maintenance policy reviewed during the survey states, "Preventative maintenance needs to be completed and documented annually." 2. The laboratory failed to provide evidence of annual preventative maintenance from 2022 for the microscope used for reading patient slides. 3. The LD interviewed on July 10, 2023 at 2:05 PM confirmed the laboratory failed to provide documentation of annual preventative maintenance from 2022 for the microscope used by the laboratory to read patient slides.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test results maintained in the Electronic Health Record (EHR), review of patients' Mohs maps and slides and interview with the laboratory director (LD), the laboratory failed to have an adequate manual system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (entered manually) to final report destination, in a timely manner. Findings include: 1. Patient-specific data and the final test result information for Mohs is manually transcribed by laboratory personnel into the patient's EHR. 2. Direct observation of the laboratory's Mohs log, patient slides and Mohs maps showed the laboratory utilizes a unique accession number for each patient's Mohs specimen (s). 3. Two out of four patient test reports reviewed in the EHR, M21-027 performed on 5/06/2021 and M23-68 performed on 3/29/2023, failed to include the unique Mohs accession number. 4. The laboratory failed to have an adequate manual system in place to ensure patient-specific data is reliably transcribed into the patient's EHR. 5. The LD interviewed on July 10, 2023 at 1:25 PM confirmed the laboratory failed to have an adequate system in place to ensure test results and other patient-specific data are reliably transcribed into the patient's EHR.