Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0870618	10/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Surgery Center Llc	6410 Rockledge Drive , #300, Bethesda, MD	

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) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 procedure manual review and interview with the histotechnician (HT), the laboratory failed to provide the testing personnel with written policies and procedures for recording room temperature and humidity, and documenting corrective actions when the measurements did not meet the laboratory's criteria for acceptability. Findings: 1. The laboratory monitors the room temperature and humidity of the room where histopathology testing is performed on the "LAB Temperature Log" and the room temperature and humidity of the room where patient slides are stored on the

	"Slide Temperature Log." 2. Procedure manual review showed that the laboratory did not have a procedure for how to measure and document the room temperature and humidity in each room, what steps to take if the measurements were unacceptable, or how to document any corrective actions taken. 3. During an interview on 10/03/2025 at 12:00 PM, the HT confirmed that the procedure manual did not contain procedures for how to document room temperatures and humidity and any corrective actions taken when the measurements were not acceptable.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on quality control (QC) and patient log record review and interview with the histotechnician (HT), the laboratory failed to ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain each day of patient testing. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides for Mohs surgery patients. Daily stain QC for the H&E stain is recorded on the "Control Slide" log. 2. A review of daily stain QC logs from January 2024 through May 2025 showed that the results of the stain QC was not documented on the "Control Slide" log on 01/12/2024, 02/06/2025, and 05/22/2025; and 3. A review of patient logs for the same time period showed that there were 12 patients tested on 01/12/2024 (case # 24-66 through 24-77); 11 patients tested on 02/06/2025 (case # 25-207 through 25-217); and 12 patients tested on 05/22/2025 (case # 25-859 through 25-870). 4. During an interview on 10/03/2025 at 12:00 PM, the HT confirmed that daily stain QC was not consistently documented.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on humidity log record review and interview with the histotechnician (HT), the laboratory failed to document corrective action when laboratory room humidity readings were out of range. Findings: 1. The laboratory documents the daily room temperature and humidity of the room where histopathology testing is performed on the "LAB Temperature Log" (lab temp log) and the room temperature and humidity of the room where patient slides are stored on the "Slide Temperature Log" (slide temp log). 2. The humidity range printed at the top of the lab temp log was "30-60%." The slide temp log did not have a humidity range listed. During an interview on 10/03 /2025 at 12:00 PM, the HT stated that the acceptable humidity range was the same for both logs. 3. A review of lab and slide temp logs from January through April 2025 showed that the humidity was out of the acceptable range 65 out of 85 times documented on the lab temp log and 64 out of 80 times documented on the slide temp log. 4. There were no corrective actions documented for the out of range humidity

	readings. 5. During an interview on 10/03/2025 at 12:00 PM, the HT confirmed that there were no corrective actions documented for the days that the laboratory humidity readings were out of range.