Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1092420	02/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sean Arvindh Sukal Md Phd Pa Dba Sukal Skin	2900 N Military Trl Ste 100, Boca Raton, FL	

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	An announced CLIA recertification survey was conducted at Sean Arvindh Sukal MD PhD PA dba Sukal Skin Institute on February 5, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 review of the procedure manual and peer review records, and interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain at least twice annually in 2023 and 2024. Findings: The laboratory used peer review to verify the accuracy of the reading and interpretation of the H&E stain. Review of the policy titled Quality Assurance /Proficiency Testing Program (In House) Section titled Diagnostic Frozen and Permanent Section Skin Specimens noted "Every six months, the histotechnologist will make a duplicate slide, label it with only the surgical case number, and send it out to a random chosen reference laboratory for Microscopic examination by a Board Certified Dermatopathologist." Review of the peer review records revealed the peer review for Testing Personnel B was found to be in agreement with the original results and signed on 02/10/2023, 08/10/2023, 2/13/2024, and 08/15/2024 by Testing Personnel B. On 02/05/2025 at 4:07 PM, the Risk Manager and CLIA Compliance Supervisor acknowledged Testing Personnel B conducted the peer review on himself.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on interview, review of quality control and patient logs, the laboratory failed to document quality control and function checks in the histopathology laboratory on 01 /31/2025. Findings: Review of the Mohs Accession Log showed there were 31 Mohs surgical procedures performed on 01/31/2025. Review of the Mohs Daily Quality Control Worksheet showed the acceptability of the Hematoxylin and Eosin stain quality, microscope verification, cryostat maintenance, cryostat temperature, room temperature and room humidity were not recorded on 01/31/2025. Review of the Hematoxylin and Eosin Staining Maintenance Log showed on 01/31/2025 the log was not filled out to indicate if the reagents used for staining slide were changed, rotated, filtered, added to, or if they were acceptable. On 02/05/2025 at 1:45 PM, the Risk Management and CLIA Compliance Supervisor acknowledge the documentation on 01 /31/25 was missing. .