Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2177989	**(X3) Date Survey Completed** 06/26/2023
Name of Provider or Supplier Skin Care Specialists, Pllc	**Street Address, City, State** 9225 Katy Freeway, Ste 404, Houston, 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 out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 laboratory's twice annual test accuracy verification documents, laboratory's policies/procedures and staff interview, the laboratory failed to document twice annual Mohs accuracy verification for 2 of 2 events in 2022. Findings included: 1. Review of laboratory's twice annual Mohs accuracy verification documents for 2021, 2022 and 2023 revealed the laboratory documented test accuracy verification as follows: 02/24/2021 09/13/2021 06/21/2023 There was no documentation for twice annual test accuracy verification for 2022. 2. Review of the laboratory's "Mohs Laboratory Procedure Manual Histopathology Mohs Surgery" (last reviewed 10/20 /2020) revealed: "PROFICIENCY TESTING ... Random selection of Mohs surgical

	cases are chosen every six months." 3. In an interview on 06/26/2023 at 0935 hours in the laboratory, facility's Regional Manager (as indicated on the laboratory's Survey and /or Complaint Investigation Entrance/Exit Conference document), after review of the data, confirmed the findings.
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 review of laboratory's definitions of temperature and humidity acceptability, laboratory's temperature records and staff interview, the laboratory failed to ensure operation of its Avantik Cryostat instrument was performed within laboratory's temperature and/or humidity specifications for 8 of 17 days the instrument was in operation. Findings included: 1. Review of laboratory's definitions of temperature and humidity acceptability revealed the laboratory defined acceptable room temeprature and humidity as follows: "Temperatures are to be no greater than 80 degrees and no less than 50 degrees (F)." And, "Humidity levels are to be no greater than 60 percent." 2. Review of laboratory's temperature/humidity records for January 2022 to May 2023 revealed the following 8 of 17 days the Avantik Cryostat instrument was in operation the laboratory's room temperature and/or humidity was out of laboratory's defined range: Date: Temperature(F)/Humidity(%) 01/26/2022 80.9F 02/23/2022 83.1F 03/23 /2022 85.1F 04/27/2022 61.6% 05/25/2022 82.4F 01/25/2023 80.9F 02/22/2023 84.1F 03/22/2023 82.3F 3. In an interview on 06/26/2023 at 1000 hours in the laboratory, facility's Regional Manager (as indicated on the laboratory's Survey and/or Complaint Investigation Entrance/Exit Conference document), after review of the data, confirmed the findings. Key: F - Degrees Fahrenheit % - Percent
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a

general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of laboratory's submitted form CMS 209, personnel records and staff interview, the laboratory failed to document identification of personnel delegated to perform grossing for 1 of 2 testing personnel employed by the facility. Findings included: 1. Review of laboratory's submitted form CMS 209 revealed the laboratory employed two testing personnel. 2. Review of personnel records revealed Testing Person number two (as indicated on submitted form CMS 209) started testing in January 2023. Personnel records for Testing Person number two did not have delegation of grossing of histopathology samples. There were no other documents identifying testing personnel delegated to perform grossing. 3. In an interview on 06/26/2023 at 0915 hours in the laboratory, facility's Regional Manager (as indicated on the laboratory's Survey and/or Complaint Investigation Entrance/Exit Conference document), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid