Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2229631	(X3) Date Survey Completed 06/03/2024
Name of Provider or Supplier Skin Care Specialists, Pllc	**Street Address, City, State** 23050 Westheimer Parkway, Katy, 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 surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
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 a review of the laboratory's policies, the laboratory's accuracy assessment records from 2022, and staff interview, the laboratory failed to have documentation of performing one of two twice annual accuracy assessments for Mohs slide interpretations in 2022. Findings include: 1. A review of the laboratory's policy titled 'Mohs Laboratory Procedure Manual Histopathology- Mohs Surgery' revealed the following: "Skin Cancer Specialists conducts a semi-annual proficiency test to ensure quality and accurate interpretation of slides from Mohs surgery cases. Random selections of Mohs surgical cases are chosen every six-months." 2. A review of the laboratory's accuracy assessment records revealed the laboratory performed one accuracy assessment in May 2022. The laboratory failed to have documentation of verifying the accuracy of the Mohs slide interpretations a second time in 2022. 3. In an interview on 6/3/24 at 9:25 a.m. in the laboratory, after review of the records, the Operations Coordinator confirmed the above 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 a review of the laboratory's policies, the Humidity and Temperature Log for 2023, patient test records, and staff interview, the laboratory failed to have documentation of monitoring the temperature and humidity in the laboratory for eight of twenty nine days from January to December 2023. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment Manual' revealed the following: "The environment in the working area of the laboratory will be controlled by commonly used heating, air-conditioning and ventilation equipment used throughout the entire medical office, which will maintain a working temperature of 50-80 degrees Fahrenheit, and humidity of less than 60%." 2. A review of the Humidity and Temperature Log for 2023 (January to December) revealed the following: "Humidity and temperature are logged to ensure proper function and storage of all mohs lab equipment." 3. Further review of the Humidity and Temperature Log for 2023 revealed the laboratory failed to have documentation of monitoring the temperature and humidity in the laboratory for the following 8 days patient specimens were tested: 6/2/23 6/16/23 7/14/23 7/28/23 8/12/23 9/15/23 10/13/23 10/27/23 4. A review of patient test records revealed the following patients were tested on days when the laboratory's temperature and humidity were not documented: Date tested: 6/2/23 Patient Case Numbers: TF23-K071, TF23-K072, TF23-K073, TF23-K074, TF23-K075, TF23-K076, TF23-K077 Date tested: 6/16/23 Patient Case Numbers: TF23-K078, TF23-K079, TF23-K080, TF23-K081 Date tested: 7/14/23 Patient Case Numbers: TF23-K091, TF23-K092, TF23-K093, TF23-K094, TF23-K095, TF23-K096, TF23-K097 Date tested: 7/28/23 Patient Case Numbers: TF23-K105, TF23-K106, TF23-K107, TF23-K108, TF23-K109, TF23-K110, TF23-K111, TF23-K112 Date tested: 8/12/23 Patient Case Numbers: TF23-K120, TF23-K121, TF23-K122, TF23-K123, TF23-K124, TF23-K125 Date tested: 9/15/23 Patient Case Numbers: TF23-K140, TF23-K141, TF23-K142, TF23-K143, TF23-K144, TF23-K145, TF23-K146 Date tested: 10/13/23 Patient Case Numbers: TF23-K153, TF23-K154, TF23-K155, TF23-K156, TF23-K157, TF23-K158, TF23-K159 Date tested: 10/27/23 Patient Case Numbers: TF23-K167, TF23-K168, TF23-K169, TF23-K170, TF23-K171, TF23-K172, TF23-K173 5. In an interview on 6/3/24 at 9:40 a.m. in the laboratory, after review of the records, the Operations Coordinator confirmed the above findings.
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 a review of the laboratory's policies, the Microscope Maintenance Logs, patient test records, and staff interview, the laboratory failed to have documentation of performing microscope maintenance procedures for eight of fifteen days from June to October 2023. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment Manual' revealed the following: "Microscope stage and ocular eyepieces are to be cleaned daily. Stage is to be cleaned with alcohol or similar cleaner and ocular eyepieces are to be cleaned with lens paper." 2. A review of the Microscope Maintenance Logs from June to October 2023 revealed the laboratory failed to have documentation of performing microscope maintenance procedures for the following 8 days: 6/2/23 6/16/23 7/14/23 7/28/23 8/12/23 9/15/23 10/13/23 10/27/23 3. A review of patient test records revealed the following patients were tested on days when the microscope maintenance procedures were not documented: Date tested: 6/2/23 Patient Case Numbers: TF23-K071, TF23-K072, TF23-K073, TF23-K074, TF23-K075, TF23-K076, TF23-K077 Date tested: 6/16/23 Patient Case Numbers: TF23-K078, TF23-K079, TF23-K080, TF23-K081 Date tested: 7/14/23 Patient Case Numbers: TF23-K091, TF23-K092, TF23-K093, TF23-K094, TF23-K095, TF23-K096, TF23-K097 Date tested: 7/28/23 Patient Case Numbers: TF23-K105, TF23-K106, TF23-K107, TF23-K108, TF23-K109, TF23-K110, TF23-K111, TF23-K112 Date tested: 8 /12/23 Patient Case Numbers: TF23-K120, TF23-K121, TF23-K122, TF23-K123, TF23-K124, TF23-K125 Date tested: 9/15/23 Patient Case Numbers: TF23-K140, TF23-K141, TF23-K142, TF23-K143, TF23-K144, TF23-K145, TF23-K146 Date tested: 10/13/23 Patient Case Numbers: TF23-K153, TF23-K154, TF23-K155, TF23-K156, TF23-K157, TF23-K158, TF23-K159 Date tested: 10/27/23 Patient Case Numbers: TF23-K167, TF23-K168, TF23-K169, TF23-K170, TF23-K171, TF23-K172, TF23-K173 4. In an interview on 6/3/24 at 9:50 a.m. in the laboratory, after review of the records, the Operations Coordinator confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of laboratory's policies, the laboratory's H&E and QC Stain Logs, patient test records, and staff interview, the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for MOHS histopathology slides each day of use for eight of fifteen days from June to October 2023. Findings include: 1. A review of the laboratory's policy titled 'Mohs Laboratory Procedure Manual Histopathology- Mohs Surgery' revealed the following: "Quality control is performed for the adequacy of staining. A daily control slide for H&E stain is documented representing stain quality for each day of use." 2. A review of the laboratory's H&E and QC Stain Logs from June to October 2023 revealed no documentation of the intended reactivity for the H&E stain on the following 8 days: 6/2/23 6/16/23 7/14/23 7/28/23 8/12/23 9/15/23 10/13/23 10/27/23 3. A review of patient test records revealed the following patients were tested on days when the intended reactivity of the H&E slide was not documented: Date tested: 6/2/23 Patient Case Numbers: TF23-K071, TF23-K072, TF23-K073, TF23-K074, TF23-K075, TF23-K076, TF23-K077

	Date tested: 6/16/23 Patient Case Numbers: TF23-K078, TF23-K079, TF23-K080, TF23-K081 Date tested: 7/14/23 Patient Case Numbers: TF23-K091, TF23-K092, TF23-K093, TF23-K094, TF23-K095, TF23-K096, TF23-K097 Date tested: 7/28/23 Patient Case Numbers: TF23-K105, TF23-K106, TF23-K107, TF23-K108, TF23-K109, TF23-K110, TF23-K111, TF23-K112 Date tested: 8/12/23 Patient Case Numbers: TF23-K120, TF23-K121, TF23-K122, TF23-K123, TF23-K124, TF23-K125 Date tested: 9/15/23 Patient Case Numbers: TF23-K140, TF23-K141, TF23-K142, TF23-K143, TF23-K144, TF23-K145, TF23-K146 Date tested: 10/13/23 Patient Case Numbers: TF23-K153, TF23-K154, TF23-K155, TF23-K156, TF23-K157, TF23-K158, TF23-K159 Date tested: 10/27/23 Patient Case Numbers: TF23-K167, TF23-K168, TF23-K169, TF23-K170, TF23-K171, TF23-K172, TF23-K173 4. In an interview on 6/3/24 at 9:40 a.m. in the laboratory, after review of the records, the Operations Coordinator confirmed the above findings. Key: QC = Quality Control *NOTE- this was a repeat deficiency from the survey performed on 5/16/22