Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2021787	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Consultants, Pa	12200 Park Central Drive, Suite 215, Dallas, 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	An announced recertification suvey conducted 03/29/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
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 Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated histopathology (Mohs) procedures at least twice annually for 2 of 2 testing events in 2022. The findings include: 1. Review of the CMS-116 form submitted at survey revealed the laboratory performed histopathology (MOHs) procedures. 2. Review of the laboratory's "Proficiency Testing" policy revealed: "MOHS MICROGRAPHIC SURGERY SKIN SPECIMENS Proficiency Testing Program in the Mohs Micrographic Cutaneous Oncology, this laboratory has instituted an Internal Quality Control Program. Quarterly, the tech or Risk Manager will pull 5% of the total number of cases for the indicated quarter per physician. It will contain the original slides, Mohs maps, and QA record sheet. These selected cases will be read by other Dermatopathologists in the practice. Once the slides are read the reports are attached and placed in the QA Notebook. In the event, the pathology report from the Dermatopathologist does NOT match the in house[sic] diagnosis by the physician, an identical slide will be sent, by the tech or risk manager to an outside laboratory chosen from the list below, for microscopic examination. Results of each Proficiency Test will be kept in the QA Notebook, as part of its permanent records ..." 3. Review of laboratory records revealed Testing Person 1 (TP1), Testing Person 2 (TP2), and Testing Person 3 (TP3)

	performed Mohs procedures. Further review of the records revealed there were no twice annual accuracy assessment records for TP1, TP2, or TP3 for 2 of 2 events 2022. The surveyor requested documentation of twice annual accuracy assessments for Mohs procedures from 2022. None were provided. 4. During an interview on 03/29 /2023 at 03:19 p.m., the Histotechnician and Office Administrator confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on laboratory policy, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers for 52 of 52 slides from October through December of 2022 and January through February of 2023 (random sampling). The findings include: 1. Review of the laboratory's policy titled "SLIDE LABELING" revealed: "1. Upon starting a new case ALL slides to be used for that case will be labeled using a permanent slide marking pen. 2. Slides are to be labeled with the patient's last name, doctor's last initial, current year, Mohs log accession number, tumor ID, specimen number, slide number and stage number. For example: Smith (patient's name), Z15 (doctor's last initial and current year), XXX (Mohs log accession number), A (tumor ID), 1.1, 1.2, 1.3 (specimen number and slide number) ..." The laboratory policy did not include labeling instructions to reliably identify patients with the same last name using unique patient identifiers to distinguish between specimens. 2. A random review of patient slides from October through December of 2022 and January through February of 2023 revealed 52 slides labeled with the patient's last name, doctor's last initial and current year, tumor ID, specimen number, slide number, and stage number. The laboratory failed to ensure patient histopathology (Mohs) slides were labeled with at least 2 unique patient identifiers. 3. During the exit interview on 03/29/2023 at 05: 00 p.m., the Histotechnician confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure tissue marking dyes stored in secondary containers were labeled with proper identification and poured/expiration dates for 4 of 4 dyes and 1 of 1 saline solutions.

	The findings include: 1. During a tour of the laboratory on 03/29/2023 at 04:44 p.m., the surveyor observed 5 unlabeled plastic jars on a countertop as follows: 1 jar containing red dye 1 jar containing green dye 1 jar containing blue dye 1 jar containing black dye 1 jar containing clear liquid During an interview on 03/29/2023 at 04:44 p.m., the surveyor asked the Histotechnician what the clear liquid was, and he stated that it was saline. The laboratory failed to label the secondary containers with the name of the material, lot numbers, and poured/expiration dates, as applicable. Without proper labeling, the tissue marking dyes and saline solution could not be linked to their original containers. 2. During the exit interview on 03/29/2023 at 4:44 p.m., Histotechnician 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 review of laboratory's policy, quality control (QC) log, patient test records, and confirmed in interview, the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for 48 of 48 days in 2022 (October to December) and 34 of 34 days in 2023 (January and February). The findings include: 1. Review of the laboratory policy titled "HEMATOXYLIN AND EOSIN STAIN" revealed: "Quality Assurance: The first case submitted to the Mohs lab will be stained with H&E and documented on the control sheet as the QA. This slide will be kept in the file for QC slides. This slide will show, blue nuclei and pink cytoplasm." 2. Review of the laboratory's "QUALITY CONTROL STAINING" logs from October 2022 to February 2023 revealed: "The first case submitted to the Mohs lab which consists of normal tissue will be stained for H&E, documented on the control sheet as the QA. This slide will be kept on file. The quality control will show blue nuclei, pink cytoplasm." Further review of the quality control logs revealed the log had a column titled "STAIN" and each day of patient testing QC was documented with a "checkmark" in the column. The laboratory failed to specify what the "checkmark" indicated. The following dates in 2022 (October to December) and 2023 (January and February) were observed to be documented with a "checkmark": 2022 October: 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 17, 18, 19, 20, 24, 25, 26, 27, 31 November: 1, 2, 3, 7, 8, 9, 10, 14, 15, 16, 17, 22, 28, 29, 30 December: 1, 5, 6, 7, 8, 9, 12, 13, 14, 15, 20, 21, 29, 30 2023 January: 3, 4, 5, 6, 9, 10, 11, 12, 13, 16, 17, 18, 19, 23, 24, 25, 16, 30 February: 3, 6, 7, 8, 9, 10, 13, 14, 15, 16, 21, 22, 23, 24, 27, 28 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. A random sampling of patient records revealed the following patients that were tested and reported when quality control was not documented: 10/04/2022 Accession #'s: P22-347, P22-352, P22-348 10/11/2022 Accession #'s: P22-364, P22-365 11/01/2022 Accession #'s: P22-393, P22-396, P22-395 12/06/2022 Accession #'s: P22-444, P22-445 01/25/2023 Accession #'s: W23-036, W23-040 02/14/2023 Accession #'s: P23-067, P23-072 4. During an interview on 03/29/2023 at 02:22 p.m., the Histotechnician and Office Administrator confirmed the above findings.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview, the laboratory failed to include the testing facility address on the final reports for 14 of 14 patients in 2022 (October to December) and 2023 (January to February). The findings include: 1. Review of patient records from 2022 and 2023 revealed the following 14 final reports (random sampling) that did not include the testing facility address: 10/04/2022 Accession #'s: P22-347, P22-352, P22-348 10/11/2022 Accession #'s: P22-364, P22-365 11/01/2022 Accession #'s: P22-393, P22-396, P22-395 12/06/2022 Accession #'s: P22-444, P22-445 01/25/2023 Accession #'s: W23-036, W23-040 02/14/2023 Accession #'s: P23-067, P23-072 2. During the exit interview at 05:00 p.m., the Histotechnician confirmed the above findings.