| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D2267035 | 05/15/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Skin Solutions Dermatology | 2130 Wilma Rudolph Blvd, Clarksville, TN | |

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 |
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| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of the laboratory procedure manual, and staff interview, the laboratory procedure for slide labeling did not include the specimen source/site or Mohs surgical stage. 1. Observation of the laboratory on 05/15 /24 at 8:20 a.m. revealed equipment used for processing and preparing patient tissue removed during Mohs surgical procedures for microscopic examination. 2. The laboratory procedure titled "Mohs Protocol" did not include requirements for slide labeling that included specimen source/site, second patient identifier or Mohs stage. 3. The practice manager confirmed the survey findings during interview on 05/15/24 at 11:30 a.m. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory procedures and staff interview, the laboratory |

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| | procedures were not approved, signed or dated by the laboratory director. The findings include: 1. A review of the laboratory procedures titled Quality Assurance Manual, Histology Protocol, Mohs Staining, Mohs Protocol, Quality Assurance Reviews, Equipment Quality Control, and Reagent Handling Protocol revealed the laboratory director had not approved, signed, or dated the procedures. 2. The practice manager confirmed the survey findings during interview on 05/15/24 at 11:30 a.m. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, review of stain quality assessment logs, and staff interview, the laboratory failed to document the expected staining characteristics for the Hematoxylin and Eosin stain for 12 of 12 days in 2024. The findings include: 1. Observation of the laboratory on 05/15/24 at 8:20 a.m. revealed equipment, stains (Hematoxylin and Eosin (H&E)) and reagents used for processing and preparing patient tissue removed during Mohs surgical procedures for microscopic examination. 2. Review of the laboratory's H&E stain quality assessment log revealed the laboratory did not document the expected staining characteristics for the H&E stain for 12 of 12 days in 2024. 3. The practice manager confirmed the survey findings during interview on 05/15/24 at 11:30 a.m. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Quality Assurance manual, lack of documented review, and staff interview, the laboratory failed to ensure quality assessment reviews were performed monthly by the Laboratory Director as required in the Quality Assurance Manual for four of five months reviewed in 2024. The findings include: 1. A review of the laboratory's Quality Assurance Manual revealed that the Laboratory Director would review charts and logs monthly. 2. Laboratory Director review was not performed timely (monthly) for January, February, March, or April 2024. 3. The practice manager confirmed that the Laboratory Director failed to review laboratory records monthly as required in the Quality Assurance Manual for four of five months reviewed in 2024 during interview on 05/15/24 at 11:30 a.m. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c) |

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| | (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Quality Assurance Manual, patient Mohs surgical log, laboratory record review, and staff interview, the laboratory's quality assessment process was not effective in identifying and correcting problems for two of two months with missing documentation in 2024. The findings include: 1. A review of the laboratory's Quality Assurance Manual revealed the following statement: "The laboratory of Skin Solutions Dermatology has established a Quality Assurance (QA) Program. It is the policy of this laboratory to apply the principles of the QA Program to all activities of this laboratory, including pre-analytic, analytic and post-analytic activities. The QA program assures the accurate, reliable and prompt reporting of test results and provides methods to evaluate the effectiveness of its policies and procedures, to identify and correct problems, and to assure the adequacy and competency of the staff." 2. A review of the patient Mohs log revealed the following: Three Mohs cases performed on 01/17/24 (Case numbers CLK24-010, CLK24-011, CLK24-012), five Mohs cases performed on 01/24/24 (Case numbers CLK24-013, CLK-014, CLK24-015, CLK24-016, CLK24-017), four Mohs cases performed on 01 /31/24 (CLK24-018, CLK24-019, CLK24-020, AND CLK24-021), and four Mohs cases performed on 03/20/24 (CLK24-040, CLK24-041, CLK24-042, CLK24-043). 3. A review of laboratory records revealed the following: No documented room temperature, humidity, or cryostat temperatures on 01/17/24, 01/24/24, or 01/31/24. No documented stain quality assessment on 01/31/24. No documented room temperature on 03/20/24. The Laboratory Director reviewed all laboratory records on 05/15/24, but no documented corrective action was taken for the missing documentation. 4. The practice manager confirmed the laboratory's quality assessment was ineffective in identifying and correcting problems with missing documentation of temperatures, humidity, and stain quality assessment in 2024 on dates when Mohs surgeries / histopathology procedures were performed during interview on 05/15/24 at 11:30 a.m. |