| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2229631 | 01/12/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Skin Care Specialists, Pllc | 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 |
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| **D0000** | An announced survey of the laboratory was conducted on January 12, 2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's policies/procedures, twice annual test accuracy verification records and staff interview, the laboratory failed to document twice annual test accuracy verification for one of two required events in 2025. Findings included: 1. Review of laboratory's policy/procedure "Quality Control" (last reviewed 02/15/2025) revealed: "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. Review of twice annual test accuracy verification records from 2025 revealed test accuracy verification was documented on 09/15/2025. There was no other documentation of test accuracy verification in 2025. 3. In an interview on 01/12/2025 at 0915 hours in the laboratory, the facility's Practice Manager (as indicated on submitted Entrance /Exit Conference document) confirmed the findings. |
| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test |

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| | result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's policies/procedures, microscope maintenance records, patient test logs and staff interview, the laboratory failed to follow its own policy and document microscope maintenance for three of three days microscope maintenance was required in January and February 2025. Findings included: 1. Review of laboratory's policy/procedure "Quality Control Program" (last reviewed 02/04/2025) revealed: "EQUIPMENT QUALITY CONTROL - MICROSCOPE 1. Microscope stage and ocular eyepieces are to be cleaned daily." And, "4. Every action is documented on the maintenance record form." 2. Review of laboratory's microscope maintenance records from January and February 2025 revealed there was no documentation of microscope maintenance documented on the following three days microscope was in use: 01/31/3035 02/14/2025 02/21/2025 3. Review of laboratory's patient test logs revealed the following patient Mohs case numbers were tested on the days microscope maintenance was not documented: Patient cases tested on 01/31 /3035: TF25-K017 TF25-K018 TF25-K019 TF25-K020 TF25-K021 TF25-K022 TF25-K023 TF25-K024 Patient cases tested on 02/14/2025: TF25-K025 TF25-K026 TF25-K027 TF25-K028 TF25-K029 TF25-K030 TF25-K031 TF25-K032 TF25-K033 Patient cases tested on 02/21/2025: TF25-K034 TF25-K035 TF25-K036 TF25-K037 TF25-K038 TF25-K039 TF25-K040 TF25-K041 TF25-K042 4. In an interview on 01 /12/2025 at 1010 hours in the laboratory, the facility's Practice Manager (as indicated on submitted Entrance/Exit Conference document) confirmed the findings. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's policies/procedures, H&E (hematoxylin and eosin) stain control records, patient test logs and staff interview, the laboratory failed to document stain acceptability for three of three days stain quality control record was required in November 2024 and February 2025. Findings included: 1. Review of policy/procedure "Quality Control" (last reviewed 02/15/2025) revealed: "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. Review of daily H&E stain acceptability logs from November 2024 and February 2025 revealed the following three days of patient testing stain acceptability was not documented: 11/22 /2024 02/14/2025 02/21/2025 3. Review of laboratory's patient test logs revealed the following patient Mohs case numbers were tested on the days H&E stain acceptability was not documented: Patient cases tested on 11/22/2024: TF24-K261 TF24-K262 TF24-K263 TF24-K264 TF24-K265 TF24-K266 TF24-K267 TF24-K268 TF24-K269 Patient cases tested on 02/14/2025: TF25-K025 TF25-K026 TF25-K027 TF25-K028 TF25-K029 TF25-K030 TF25-K031 TF25-K032 TF25-K033 Patient cases tested on 02/21/2025: TF25-K034 TF25-K035 TF25-K036 TF25-K037 TF25-K038 TF25-K039 |

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| | TF25-K040 TF25-K041 TF25-K042 4. In an interview on 01/12/2025 at 1010 hours in the laboratory, the facility's Practice Manager (as indicated on submitted Entrance /Exit Conference document) confirmed the findings. |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's policies/procedures, Quality Assessment (QA) monthly reports and staff interview, the laboratory's QA failed to identify and correct issues with H&E stain acceptability and microscope maintenance for one of one laboratory's test platforms, histologic examination of Mohs surgery tissues. Findings included: 1. Review of laboratory's policy/procedure "Quality Assessment Manual" (last reviewed 02/04/2025) revealed: "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." And, "The Laboratory Director reviews all quality control charts and logs on at least a monthly basis. ... The Laboratory Director will review the corrective action to ensure that appropriate action is taken and proper procedures were followed." 2. Review of laboratory's monthly QA reports revealed the laboratory's QA processes failed to identify issues with documentation of H&E (hematoxylin and eosin) stain acceptability and microscope maintenance. No corrective action was documented. Cross refer to D5433 and 5473. 3. In an interview on 01/12/2025 at 1010 hours in the laboratory, the facility's Practice Manager (as indicated on submitted Entrance/Exit Conference document) confirmed the findings. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's policies/procedures, quality control (QC) records, microscope maintenance records, Quality Assessment (QA) monthly reports and staff interview, the laboratory director failed to ensure laboratory's QC/QA was maintained for one of one laboratory's test platforms, histologic examination of Mohs surgery tissues. Refer to D5433, D5473 and D5791. |