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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D2180046          | <b>(X3) Date Survey Completed</b><br>07/09/2025 |
| <b>Name of Provider or Supplier</b><br>Austin Skin   | <b>Street Address, City, State</b><br>1501 B Dorothy Nichols Rd, Smithville, TX |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D0000</b>              | 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. Standard level deficiencies were cited.  |
| <b>D5311</b>              | <p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b><br/>CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's policies and procedures, slide review, and interview, the laboratory failed to ensure slides for Mohs testing were labeled correctly for one of 12 Mohs cases reviewed. Findings follow. Review of the laboratory's policy and procedure titled Histopathology- Mohs Surgery, reviewed 05/30/2025, at the Specimen Requirements section 3 stated, "3.4.10 Laboratory technician will cut frozen sections and stain. Slides are labeled with unique case number, patient's last name, first name, date of procedure, stage (designated with Roman numerals [I, II, III, ...]), piece, and slide letter. 3.4.11 After cover slips are applied, the labeled slides are brought to Mohs surgeon with a Mohs map for evaluation." Review of second stage slide for Mohs case CS25-544 from 06/25/2025 was labeled incorrectly (CS25-544 II) as the patient's chart and Mohs maps showed the case had only one stage. Further review showed case CS25-545 was missing a slide for stage II as the chart notes and Mohs maps indicated there were two stages and there were only slides for one stage. Interview with the histotechnologist on July 9, 2025 at 1600 in the office confirmed the slide labeled CS25-544 II belonged to case</p> |

CS25-545 and should have been labeled CS25-545 II. In addition, the diagnosis of Basal Cell Carcinoma on the slide CS25-544 II was consistent with the case CS25-545 versus case CS25-544 which had Squamous Cell Carcinoma

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the patient testing log, patient test report, and interview, the laboratory failed to ensure the correct result was reported for the KOH (potassium hydroxide) test for fungal elements for one of two test reports reviewed from 01/10/2025 - 05/12/2025. Findings follow. Review of the patient testing log from 01/10/2025 - 05/12/2025 against the patient test report showed one of two with the incorrect result. Review of the KOH log showed patient tested on 01/10/2025 for K25-002 was reported as negative. Review of the corresponding patient chart on 01/10/2025 showed the KOH was reported as branching hyphae. Interview with the Supervisor on July 9, 2025 at 1630 hours confirmed the result was negative and incorrectly reported as positive in the chart by a medical assistant.