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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D2019934        | <b>(X3) Date Survey Completed</b><br><br>10/06/2026 |
| <b>Name of Provider or Supplier</b><br><br>Tru-Skin Dermatology                                                            | <b>Street Address, City, State</b><br><br>3101 Hwy 71 East Suite 203, Bastrop, 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              | The Tru-Skin Dermatology laboratory in Bastrop was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 10/06 /2026 and recertification is recommended. Standard level deficiencies were cited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| D5805              | <p>TEST REPORT<br/>CFR(s): 493.1291(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:<br/>I. Based on review of the patient test reports, Mohs map, slides, pre-survey paperwork, and interview, the laboratory failed to include a stage in the test report for one out of six Mohs test reports reviewed from October 2024 - September 2026. Findings follow. A. Review of six randomly selected Mohs cases from October 2024 - September 2026 showed Mohs case B26-070 from 04/29/2026 was missing a Stage in the visit notes which also served as the patient test report. Review of the visit notes for the Mohs Surgery only documented 1 stage. B. Review of the Mohs maps for case B26-070 showed there were 2 stages. C. Review of the case slides for case B26-070 showed slides labeled for stages 1 and 2. D. Review of the CMS Form 116 showed an annual test volume of 250 blocks per year in Mohs. E. Interview with the Regional Director of Operations on October 6, 2026 at 1045 hours confirmed the findings. II. Based on review of the Mohs test report and interview, the laboratory failed to include</p> |

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|              | <p>the correct address of the facility on the test report for one of six cases reviewed from October 2024 - September 2026. Findings follow. A. Review of the chart notes showed an incorrect address of the facility where the testing was performed as listed by case number and date of service: B25-210 on 12/16/2025. B. Interview with the Regional Director of Operations on October 6, 2026 at 1050 hours confirmed the findings.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>D6127</b> | <p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b><br/>CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's policy and procedure, pre-survey paperwork, competency evaluations, and interview, the technical supervisor failed to evaluate the competency at least semiannually during the first year the individual tested patient specimens for one of one new testing personnel/Mohs surgeon performing diagnostic interpretations in Mohs. Findings follow. A. Review of the laboratory's policy and procedure titled Competency Assessment Protocol, updated 11/2024, stated, "Annual Competency Assessment must be performed by the lab director on individuals responsible for high complexity testing. The histotechnician will add reminder dates for the completion of the assessment to be done annually. The manager will monitor to ensure this is done annually. For new employees, there will be 2 competency assessments during the 1st year." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #2 (as listed on the CMS form 209) began Mohs testing 08/22/2025 (elapsed time 1 year, 1 month, 14 days). C. One additional semi-annual competency evaluation for testing personnel #1 was requested on October 6, 2026 at 1035 hours but not provided. D. Interview with the Regional Director of Operations on October 6, 2026 at 1035 hours confirmed only one competency evaluation was performed in the first year of testing. * This is a repeat deficiency from the 02/06/2025 survey.</p> |