Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2019934	02/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Tru-Skin Dermatology	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
D0000	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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (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. This STANDARD is not met as evidenced by: 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 seven Mohs cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Slide Labeling stated, "2. Slides are to be labeled with MOHS log accession number, DOB, Stage #1, 2, 3, etc., Block #1, 2, 3, etc., and Slide #." B. Review of slides for the Mohs cases showed B24-129 from 11/02 /2024 was labeled incorrectly. Three of six slides for case B24-129 showed the wrong date of birth, 1/25/71, an identifier on the slides. Review of the patient's chart showed a date of birth of 11/25/71. C. Interview with the Regional Director of Operations on February 6, 2025 at 1330 hours confirmed the findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of quality control (QC) records, Mohs logs, and interview, the laboratory failed to document the performance of the Hematoxylin and Eosin quality control for the intended reactivity to ensure predictable staining characteristics used to stain specimens for dermatopathology interpretations for two of 20 days of Mohs testing reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled, Quality Assurance for Routine Stains, stated, "1. A quality control slide will be run each day the lab operates. 2. The QC (quality control) slide will be for Hematoxylin and Eosin and/or Toluidine blue. Whichever is used in the lab. 3. The QC for the H&E will be of normal skin, have a crisp blue nuclei and counter stain with light pink cytoplasm... The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart. Any corrections needed for that day will be addressed at that particular time and all changes will be documented." B. Review of the quality control log from 06/17/2023 - 01/18/2025 covering 20 days of Mohs testing showed two days where QC was not documented: 11/02/2024 and 12/14/2024. C. Review of the Mohs logs showed 24 patients had been tested: 1. 11/02/2024: Mohs cases B24-118 to B24-130 2. 12/14/2024: Mohs cases B24-131 to B24-141 D. Interview with the Regional Director of Operations on February 6, 2025 at 1305 hours confirmed the findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (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. This STANDARD is not met as evidenced by: 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 testing personnel performing Mohs testing. Findings follow. A. Review of the laboratory's policy and procedure titled Competency Assessment Protocol, approved 06/28/2021, stated, "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." The policy and procedure did not address new employees twice per year competency evaluations in the first year. B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #1 (as listed on the CMS form 209) was hired 03/2023. C. One additional semi-annual competency evaluation for testing personnel #1 was requested on February 6, 2025 at 1240 hours but not provided. D. Interview with the Regional Director of Operations on February 6, 2025 at 1240 hours confirmed only one competency evaluation was performed in the first year of testing.