

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1056432	(X3) Date Survey Completed 09/21/2026
Name of Provider or Supplier Tru-Skin Dermatology	Street Address, City, State 3500 Jefferson Street Suite 200, Austin, 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 Tru-Skin Dermatology laboratory in Austin 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 09/21 /2026 and recertification is recommended. Standard level deficiencies were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, reagent log, patient testing logs, pre-survey paperwork, and interview, the laboratory failed to ensure chemicals and stains used in the Hematoxylin and Eosin (H&E) stain used to process Mohs specimens had not exceeded their expiration date by five out of 24 days of testing in 2025 and 2026. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance for Routine Stains, reviewed 11/15/2025, stated "All reagents and supplies used in the lab will be documented upon opening and put in use. This will consist of open date, lot number, [and] expiration date." Review of the laboratory's policy and procedure titled Quality Assurance for Routine Stains and the policy and procedure titled Stain Maintenance, reviewed 11/15/2025, did not address expiration dates. B. 1. Review of the Reagent Log showed Hematoxylin, Lot # 203259, expiration 01/31/2026 was opened on 1/23/2026. The next bottle of Hematoxylin was open 04/02/2026, showing an elapsed expiration of 61 days. 2. Review of the Reagent Log showed Vintage Bluing, Lot # 168096, expiration 03/31 /2026 was opened on 1/23/2026. The next bottle of Vintage Bluing was open 07/08 /2026, showing an elapsed expiration of 99 days. C. Review of the Mohs Surgery Log from 02/01/2026 - 07/07/2026 showed five days of Mohs testing with expired

	Hematoxylin or Vintage Bluing with 73 cases reported: M26-014 - M26-087. D. Review of the CMS Form 116 showed an annual test volume of 250 blocks per year in Mohs. E. Interview with the Histotechnologist on September 21, 2026 at 1000 hours confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) (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. This STANDARD is not met as evidenced by: 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 two out of eight Mohs test reports reviewed from October 2024 - August 2026. Findings follow. A. Review of eight randomly selected Mohs cases from October 2024 - August 2026 showed Mohs cases M25-087 and M26-037 were 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 cases M25-087 and M26-037 showed there were 2 stages. C. Review of the case slides for cases M25-087 and M26-037 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 September 21, 2026 at 1110 hours confirmed the findings.