Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1056432	**(X3) Date Survey Completed** 11/09/2022
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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, observation, interview, query, and pre-survey paperwork, the laboratory failed to ensure the Osom hCG Urine Control Set used for Pregnancy tests had not been used after its expiration date. Findings follow. A. Review of the Osom hCG Urine Control Set package insert, 3076-3 06/15, under Warnings and Precautions stated, "DO NOT use the Controls beyond the expiration date." B. During a tour of the laboratory on November 9, 2022, at 1115 hours in the laboratory, the surveyor observed the Osom hCG Urine Control Set, Lot 201211,

	expiration 10/31/2021 in the laboratory refrigerator. No other controls were in the laboratory. C. Interview with the medical assistant on November 9, 2022, at 1115 hours said she "just ran out and threw away the old box". D. Query of McKesson orders as far back as 03/2021 showed no urine controls had been ordered. E. Interview with the Practice Director on November 9, 2022, at 1130 hours in the breakroom agreed it didn't look like any other controls existed since it would be unlikely for controls to have been reordered prior to 03/2021 when the known set of controls didn't expire until 10/21. F. Review of pre-survey paperwork showed approximately 150 pregnancy tests were performed annually. KEY: hCG = human Chorionic Gonadotropin
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. 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 retain slides from its Mohs cases for at least 10 years for 52 out of 55 cases from Nov 2012 - Feb 2013. Findings follow. A. Review of the laboratory's policy and procedure titled Storage of Diagnosed Slides, approved on 09/26/2022, stated, "In this facility, diagnosed slides will be stored in the following manner: ...4. Slides are kept for a total of ten years." B. Review of slide retention showed slides from case number M12-150 to M12-180 from November 19, 2012, to December 17. 2012 and case number M13-001 to M13-022 from January 9, 2013, to February 28, 2013, were unavailable for review. C. Interview with the histotech on November 9, 2022, at 1100 in the breakroom confirmed she had slides from cases M13-023 and higher.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Mohs patient reports and interview, the laboratory failed to include the Mohs case number on the Mohs report for four out of 10 cases reviewed from September 2022 to December 2020. Findings follow. A. Review of the laboratory's policies and procedures showed no procedure for ensuring the Mohs case was on the patient chart. B. Review of the laboratory's Mohs patient reports showed the Mohs case number was missing for cases 1. M21-

	073, 2. M21-009, 3. M20-070, 4. M20-066. C. Interview with the Clinic Manager on November 9, 2022, at 1155 in the breakroom acknowledged it was the same Medical Assistant who did not include the Mohs case number in the report.