

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1088909	(X3) Date Survey Completed 09/14/2022
Name of Provider or Supplier Tru-Skin Dermatology	Street Address, City, State 2 St Marks Place Suite 140, La Grange, 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.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, interview, and pre-survey paperwork showed the laboratory failed to ensure the Mohs procedures were signed and dated by the laboratory director prior to use. Findings follow. A. Review of the Mohs Policies and Procedures showed the line for the Laboratory Directors' approval and date were blank. B. Interview with the Clinic Manager on September 14, 2022, at 1120 hours in the breakroom confirmed the findings. C. Review of the CMS form 116 showed an estimated annual test volume of 140 for Mohs. II. Based on review of the laboratory's policies and procedures, testing logs, and interview, the laboratory failed to ensure the KOH (potassium hydroxide) procedure for fungal elements was signed and dated by the laboratory director prior to use. A. Review of the KOH policy and procedure showed the procedure was not signed and dated by the Laboratory Director. B. Review of the patient testing logs showed KOH testing began on 03/30/2022 and 14 patients had been tested. C. Interview with the Clinic Manager on September 14, 2022, at 1040 hours in the breakroom confirmed the findings.</p>
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation, manufacturer's instructions, interview, and test logs, the laboratory failed to ensure reagents had not exceeded their expiration date for KOH (potassium hydroxide) testing for fungal elements for 18 of 18 months. Findings follow. A. During a tour of the laboratory on September 14, 2022, at 1215 hours, the surveyor observed a bottle of Delasco Potassium Hydroxide 10% with DMSO next to the microscope in the provider office. B. The bottle of Delasco Potassium Hydroxide 10% with DMSO, Lot K18294, had an expiration date of 2021/02/28: 1yr, 6 months, and 18 days expired. C. Interview with the Clinic Manager on September 14, 2022, at 1215 hours in the provider office confirmed the findings. D. Review of patient testing logs from 03/30/2022 - 09/14/2022 showed 14 patients had been tested.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures, testing logs, and interview found that the laboratory director failed to ensure that all procedures available to testing personnel had been approved signed in dated by the current laboratory director. (See 5407 I & II).