

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1088909	(X3) Date Survey Completed 11/20/2024
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	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.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of accuracy assessments and interview, the laboratory failed to verify the accuracy of its KOH (potassium hydroxide) for fungal elements at least twice annually for two of two years reviewed in 2022 and 2023. Findings follow. A. Accuracy assessments for KOH in 2022 and 2023 were requested on 11/20/2024 at 1140 hours but not provided. B. Interview with the Regional Director of Operations on November 20, 2024 at 1140 hours confirmed they did not perform twice per year accuracy assessments for KOH in 2022, 2023, nor to survey date in 2024.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for 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: Based on review of the laboratory's policy and procedure, pre-survey paperwork, competency evaluations, and interview, the technical supervisor failed to evaluate the</p>

competency at least semiannually during the first year the individual tested patient specimens for one of two semi-annual competency evaluations in Mohs testing. Findings follow. A. Review of the laboratory's policy and procedure titled Competency Assessment Protocol, effective 06/28/2021, 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." The policy and procedure did not address new employees testing within 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 05/13/2023. C. Review of the semi-annual competency evaluations for testing personnel #1 revealed only one performed in the first year on 09/30/2023. D. Interview with the Regional Director of Operations on November 20, 2024 at 1125 hours confirmed one semi-annual competency evaluation was not performed.