

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1056432	<b>(X3) Date Survey Completed</b> 05/27/2021
<b>Name of Provider or Supplier</b> Tru-Skin Dermatology	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, quality assurance records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS surgical procedures in 2020. Findings included: 1. Review of the laboratory's own policy titled ANNUAL PEER TO PEER REVIEW PROTOCOL (tru-skin) dated 04/04/2017 found: " annually, the tech or Lab Director will select a total off two mohs cases from one of the following clinics: Bastrop, LaGrange, Kerrville or Austin. They will choose one stage 1 case and one stage 2 case for submission within the current year. A completed case submission form, slides and a copy of the original mohs map will be submitted to Dr. [name omitted] or Dr. [name omitted] for final review. Once the Mohs surgeon has reviewed and signed off on the two cases, copies of both reports will be placed in each clinics PEER TO PEER REVIEW binder and recorded in the PEER TO PEER REVIEW calendar." 2. Review of peer review records found one case for the assessment of accuracy of results for the Mohs testing performed in 2020. Additional peer reviews were requested but not provided. 3. Interview of the practice manager conducted on May 27, 2021 at 09:47 AM confirmed there were no other peer reviews for Mohs procedures conducted in 2020 available for review.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Review of policies and procedures and interview of facility personnel found the laboratory failed to follow their own quality assessment procedure to monitor, assess and correct problems identified in the analytic systems in 2020. The findings included: 1. Review of policies and procedures found in the policy titled Quality assessment( signed 03/05/2018) " Annually the tech will check off the quality assessment program for procedures used in the office. The checklist is used to evaluate general laboratory systems, preanalytic systems, analytic systems and post analytic systems." Checklists for 2020 were requested but not provided. 2. Interview of the histotechnician conducted on May 27, 2021 at 09:32 AM confirmed that the laboratory did not complete the quality assurance activities in 2020.