

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1088909	<b>(X3) Date Survey Completed</b>  09/17/2018
<b>Name of Provider or Supplier</b>  Tru-Skin Dermatology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 the laboratory records, policies and procedures quality assurance records from 2017 through 2018, patient test records for 2017 and 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for KOH preparations in 2017 and 2018. Findings included: 1. Review of patient test records found that the laboratory tested 1 patient specimen for KOH between July 13, 2016 and September 17, 2018 2. Review of the policy / procedure titled KOH PEER TO PEER SLIDE PREP REVIEW - " Providers using KOH slide prep for diagnosis must log at least twice annually their slide prep date, patient and results in the KOH Slide Prep Journal found next to the microscope in the provider's office. The provider must then notify the next provider to be in office to read and confirm the slide results. The reviewing provider, date of review and review results should be recorded in the KOH Slide Prep Journal. Results should be communicated back to the originating providers. In the case of discrepancy, the Laboratory Director should be notified for separate review and confirmation. 3. A review of the laboratory's quality assurance checklists from 2017 (dated 02/22/2017) and 2018 (3/8/18) found on page 2 under KOH TESTER COMPETENCY PROFICIENCY will be assessed twice annually by laboratory director. This will be conducted by using blind samples. There was no documentation on the annual quality assurance checklist that this had been evaluated to ensure the quality assessment program identified and corrected problems. 4. An interview with the chief operation officer conducted on September 17, 2018 at 2:31 PM confirmed the laboratory was neither enrolled in a proficiency testing program nor did the laboratory verify the accuracy of the test results for KOH at least twice each year in 2017 and 2018.</p>