

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2127089	<b>(X3) Date Survey Completed</b>  05/25/2018
<b>Name of Provider or Supplier</b>  Skin Unlimited	<b>Street Address, City, State</b>  790 Generations Dr, Ste 200, New Braunfels, 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>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<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 the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for KOH and histology slides in 2017. The findings were: 1. A review of the laboratory's test menu revealed the facility performed KOH and histology testing in 2017. 2. A review of the laboratory's records revealed the facility accuracy assessments on the following patient specimens in 2017: a) Histology LS17-327 LS17-613 The assessment was not performed until May 2018. b) KOH No documentation of twice annual accuracy assessment in 2017. 3. The laboratory was asked to provide documentation of performing twice annual competency assessments for histology and KOH in 2017. No documentation was</p>

provided. 4. An interview with the office manager on 05/25/2018 at 1100 hours by the front desk confirmed the facility had not performed accuracy assessments twice in 2017 for KOH and histology slides. This confirmed the findings.