

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2181242	<b>(X3) Date Survey Completed</b>  05/21/2021
<b>Name of Provider or Supplier</b>  Sonterra Dermatology Pllc	<b>Street Address, City, State</b>  1314 E Sonterra Blvd, Ste 2201, San Antonio, 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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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><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's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for MOHS slides. The findings were: 1. A review of the laboratory's records revealed the facility started testing in May 2020. 2. Further review of the records revealed the facility had an accuracy assessment for MOHS slides performed in May 2021. 3. The facility was asked to provide documentation of a second accuracy assessment performed from May 2020 to May 2021. No documentation was provided. 4. An interview with the practice manager on 05/21/2021 at 0925 hours in the break room confirmed the findings.</p>

**D5601****HISTOPATHOLOGY**

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's H&E quality control logs from 2020 and 2021, review of patient test records from 2021, and staff interview it was revealed the laboratory failed to have documentation of evaluating control slide results on days of patient testing. The findings were: 1. A review of the laboratory's H&E quality control logs from 2020 and 2021 revealed the laboratory failed to have documentation of evaluating the stain quality from January 1, 2021 to March 10, 2021. 2. A review of patient test records revealed the following days where patient slides were stained and read: a) January 14, 2021 Case: 160 Case: 161 Case: 162 Case: 163 Case: 164 Case: 165 b) January 20, 2021 Case: 166 Case: 167 Case: 168 Case: 169 Case: 170 Case: 171 Case: 172 Case: 173 c) January 28, 2021 Case: 174 Case: 175 Case: 176 Case: 177 d) February 25, 2021 Case: 178 Case: 179 Case: 180 Case: 181 Case: 182 Case: 183 3. The laboratory was asked to provide documentation of assessing the stain quality on the identified days. No documentation was provided. 4. An interview with the practice manager on 05/21/2021 at 0943 hours in the break room confirmed the findings.