

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2009489	<b>(X3) Date Survey Completed</b>  08/09/2018
<b>Name of Provider or Supplier</b>  Sonterra Dermatology Pllc	<b>Street Address, City, State</b>  2632 Broadway Street, Suite 201 N, 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>An entrance conference was held 08/09/2018 with the Laboratory Director. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 08/09/2018, this facility was found to be in substantial compliance for the specialties/subspecialties in which it was surveyed. An exit conference was held 08/09/2018 with the Laboratory Director. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. An opportunity for questions and comments was provided.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, laboratory records, and staff interview, it was revealed that the laboratory's Quality Assurance (QA) plan failed to identify discrepancies in the evaluation of the Potassium hydroxide (KOH) twice annual verification assessments. Findings included: 1. The laboratory's procedure titled "KOH Procedure: Potassium Hydroxide (KOH) Examination of Skin, Hair, or Nails" stated "Any discrepancies will be noted and remediation will be offered, if necessary. These results will be monitored in the monthly QA checklist performed by the Laboratory director." 2. Review of the laboratory record titled "Proficiency Testing: KOH Review Form" stated the following questions: Do you concur with the results: Yes/No Any corrective action needed: Yes/No The following dates had responses that required review: a. 06/08/017 Do you concur with the results: (No response circled) Any corrective action needed: (No response circled) b. 11/01/2017</p>

Any corrective action needed: Yes c. 11/15/2017 Any corrective action needed: Yes d. 04/10/2018 Do you concur with the result: No Any corrective action needed: No 3. During an interview with the laboratory director on 08/09/2018 at 2:4 5PM in the office, the laboratory director stated "This was an oversight on my part." When asked for documentation of QA review, none was provided. This confirmed the findings.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:  
Based on direct observation, laboratory records, and staff interview, the laboratory failed to establish an ongoing mechanism to detect and correct problems when labeling patient specimen slides for 1 of 3 patients. 1. Review of a random sampling of patient test slides revealed the following: a. 3 of 3 specimen slides for Patient P17-613 were NOT labeled with the correct patient name. b. 6 of 6 specimen slides for Patient P17-612 were NOT labeled with the correct patient name. 2. Review of the laboratory's log titled "MOHS LOG" revealed: a. Patient P17-612's name was written on Patient P17-613's slides. b. Patient P17-613's name was written on Patient P17-612's slides. 3. During an interview on 08/09/2018 at 3:30PM in the office, the laboratory was asked for documentation of detection or corrective action. No documentation was provided. The laboratory director stated, "This was an oversight. We will address the issue." This confirmed the findings.