

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2079933	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Schweiger Dermatology, Pc - Elmer	Street Address, City, State 399 Front Street, Elmer, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory records, procedure manual and interview with the Laboratory Director (LD), the laboratory failed to establish a maintenance protocol for Linistain automated stainer when protocols were not provided by the manufacturer from 9/7/16 to the date of survey. The LD confirmed on 8/16/18 at 10:30 am that the laboratory did not establish maintenance protocol.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the LD failed to ensure that results of Histopathology tests received from the reviewer were reviewed and evaluated for the</p>

calender years 2016 and 2017. The LD confirmed on 8/16/18 at 10:15 am that the BA records were not reviewed and evaluated.