

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0983885	<b>(X3) Date Survey Completed</b> 11/10/2021
<b>Name of Provider or Supplier</b> Schweiger Dermatology, Pc -	<b>Street Address, City, State</b> 140 Sylvan Avenue, Englewood Cliffs, NJ	
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>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 surveyor review of the Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Histopathology testing twice annually in the calendar year 2020. The OM confirmed on 11/9/21 at 1:00 pm that the laboratory did not perform BA for Histopathology testing twice in 2020.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Fume Hood maintenance from May 2020 to the date of the survey. The findings include: 1. The PM stated the "preventive maintenance will be done on the fume hood on the same schedule as the cryostat maintenance" 2. There was no documented evidence that any preventive maintenance was performed. 3. The OM confirmed on 11/9/21 at 12:30 pm that the laboratory did not follow the PM.</p>

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Records (PR) and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the education records were available for all Testing Personnel (TP) on the date of the survey. The finding includes: 1. Education records were not available for one out of three TP. 2. The OM confirmed on 11/9/21 at 1:15 pm that education records were not available.