

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2172817	<b>(X3) Date Survey Completed</b> 10/10/2023
<b>Name of Provider or Supplier</b> Schweiger Dermatology Group	<b>Street Address, City, State</b> 501 Gordon Drive, Exton, PA	
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 lack of documentation and interview with the General Manager (GM) , the laboratory failed to verify twice annually the accuracy of Potassium Hydroxide (KOH) and Scabies microscopic examinations from 02/02/2022 through the date of the survey. Findings include: 1. On the day of survey, 10/10/2023 at 10:58 am, the laboratory could not provide documentation of verification of accuracy for KOH and Scabies microscopic examinations performed from 02/02/2022 through the date of the survey. 2. The laboratory could not provide a procedure for the verification of accuracy for KOH and Scabies upon request by the surveyor. 3. The laboratory reported a total of 17 tests were performed annually (CMS116). 4. The GM confirmed the findings above on 10/10/2023 at 11:35 a.m.</p>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the General</p>

Manager (GM), the laboratory failed to document a positive and negative control each day of patient testing for Potassium Hydroxide (KOH) and Scabies microscopic examinations from 02/10/2022 to 06/21/2023. Findings include: 1. On the day of survey 10/10/2023 at 10:39 am, review of KOH and Scabies QC records revealed the laboratory did not document the positive and negative visual control every day of patient testing . 2. The KOH and scabies examination procedure did not include a step to check visual quality control. 3. The laboratory reported a total volume of 17 tests were performed annually (CMS116). 4. The GM confirmed the above findings on 10 /10/2023 at 11:35AM.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with General Manager (GM), the Technical Consultant (TC) failed to evaluate and document the annual competency for 2 of 4 Testing Personnel (TP) who performed Potassium Hydroxide (KOH) and Scabies microscopic examinations from 02/02/2022 to date of survey. Findings include: 1. On the day of survey 10/10/2023 at 10:12 am, the laboratory could not provide documentation of the annual competency assessment for KOH and scabies for TP #3 and TP #4 (CMS209 personnel number 3 and 4). 2. GM confirmed the finding above on 10/10/2023 at 11:35am.