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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D2171014          | <b>(X3) Date Survey Completed</b><br>11/01/2023 |
| <b>Name of Provider or Supplier</b><br>Schweiger Dermatology Group   | <b>Street Address, City, State</b><br>50 Monument Rd, Ste #301, Bala Cynwyd, 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>   |
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| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>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:<br/>Based on lack of documentation, review of the laboratory's procedure manual, and interview with the Assistant General Manager (AGM), the laboratory failed to perform twice annually the verification of accuracy of Mohs microscopic examinations from 12/02/2021 to the date of survey. Findings include: 1.On the day of survey, 11/01/2023 at 10:45 AM, the laboratory could not provide the biannual documentation for the verification of accuracy of Mohs microscopic examinations from 12/02/2021 to the date of survey. 2.According to the laboratory's proficiency testing policy, "peer review will be conducted twice a year. For each test performed, a set of representative samples (at least 2 for Mohs) will be reviewed in a blinded fashion". 3.The laboratory reported an annual volume of 119 microscopic examinations/tests performed in histopathology (CMS 116). 4.The AGM confirmed the above findings on 11/01/2023 at 12:00 PM.</p> |
| <b>D5449</b>              | <p>CONTROL PROCEDURES<br/>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--<br/>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)<br/>The laboratory must document all control procedures performed.</p>  |

This STANDARD is not met as evidenced by:  
Based on review of quality control (QC) records and interview with the Assistant General Manager (AGM), the laboratory failed to document a positive and negative control each day of patient testing for Potassium Hydroxide (KOH) microscopic examinations from 12/02/2021 to 11/01/2023. Findings include: 1. On the day of survey 11/01/2023 at 11:00 AM, the laboratory failed to provide positive and negative visual control for KOH examination for each day of patient testing from 12/02/2021 to 11/01/2023. 2. According to laboratory's KOH examination procedure, each KOH slide must be determined to be acceptable or unacceptable by circling "Good" or "Poor" quality control. The provider will then sign each test entry. 3. The laboratory performed 137 mycology tests in 2022 (CMS116). 4. The AGM confirmed the above findings on 11/01/2023 at 12:00 PM.

**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 the Assistant General Manager (AGM), the Technical Consultant (TC) failed to evaluate the competency assessment for 3 of 3 Testing Personnel (TP) who performed moderate complexity testing in mycology from 12/02/2021 to 11/01/2023. Findings include: 1. On the day of survey 11/01/2023 at 11:00 AM, the laboratory failed to provide competency assessment records for 3 of 3 TP (CMS 209 personnel #1, #3, #4) who performed moderate complexity testing in mycology from 12/02/2021 to the date of survey. 2. AGM confirmed the findings above on 11/01/2023 around 12:00 PM.