

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1023143	<b>(X3) Date Survey Completed</b> 03/22/2018
<b>Name of Provider or Supplier</b> Schweiger Dermatology, Pc - Millburn	<b>Street Address, City, State</b> 12 East Willow Street, Millburn, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on six out of six TP in the calendar years 2016 and 2017. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done for Dermatopyte Test Medium (DTM). 2. Assessment of problem solving skills was not documented on CA for six out of six TP for DTM.. 3. CA was not performed for Mohs testing. 4. The TP # 4 listed on CMS form 209 confirmed on 3/22/18 at 10:20 am that the CA procedure was not performed correctly.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate coded Dermatophyte Screen PT results obtained from the Medical Laboratory Evaluation (MLE) for the 2017 - M3 PT event. The finding includes: 1. There was no review or</p>

	<p>evaluation documented when the laboratory received "Not Graded" results for specimen DM-5. 2. The TP #2 listed on CMS form 209 confirmed on 3/22/18 at 10:15 am that the laboratory did not evaluate all PT results.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 Testing Personnel (TP), the laboratory failed to perform BA twice a year for Histopathology in the calendar year 2017. The TP # 4 confirmed on 3/22/18 at 11:45 am that BA was not performed twice in 2017.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Records (TR) and interview with the Testing Personnel (TP) the laboratory failed to monitor and record the Temperature where Dermatophyte Test Medium (DTM) were incubated and stored from 1/6/16 to the date of the survey. The finding includes: 1. A review of the TR revealed DTM storage and incubator temperature was not monitored daily. 2. The TP #2 listed on CMS form 209 confirmed on 3/22/18 at 10:45 am that temperature was not monitored and recorded daily.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to evaluate the competency of six out of six Testing Personal (TP) in the calendar years 2016 and 2017. The finding includes: 1 . CA was evaluated by TP # 2 listed on CMS form 209 who had a high school diploma and was not qualified to perform CA 2. The TP #4 listed on CMS form 209 confirmed on 3/22/18 at 11:40 am that the TC did not perform CA.</p>