

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0983885	<b>(X3) Date Survey Completed</b> 11/01/2023
<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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 Maintenance Records (MR), the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to ensure the Linistat Linear Stainer maintenance was performed annually from December 2022 to the date of survey. The finding includes: 1. The PM stated " The Laboratory Director will ensure that the periodic maintenance, function checks and calibration verifications will be performed each year as required by the manufacturer. Preventative maintenance is to be performed once a year also." 2. The Linistat Linear Stainer had a maintenance label stating maintenance was due on 12/22. 3. The OM confirmed on 11/1/23 at 3:00 pm that the laboratory did not ensure maintenance was performed annually.</p>
<b>D5787</b>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)</p>

The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Mohs Surgical Log (MSL), Test Records (TR), and interview with the Office Manager (OM), the laboratory failed to maintain an accurate information system for Histopathology tests from 10/26/23 to the date of survey. The findings include: 1. A review of the Mohs Surgical log revealed: a. The date on the MSL says the calendar year of 2022, but the tests performed were on 10/26/23. b. The Case # on the MSL starts with the number 22, but should have started with the number 23 for tests performed on 10/26/23. c. Case # 22-211 was documented on the MSL having a testing date of 10/26/23, but the slides and Mohs map were documented as 23-111. d. Case #22-212 was documented on the MSL having at testing date of 10/26/23, but the slides and Mohs map were documented as 23-112. e. Case #22-213 was documented on the MSL having at testing date of 10/26/23, but the slides and Mohs map were documented as 23-113. f. Case #22-214 was documented on the MSL having at testing date of 10/26/23, but the slides and Mohs map were documented as 23-114 g. Case #22-215 was documented on the MSL having at testing date of 10/26/23, but the slides and Mohs map were documented as 23-115. 2. The OM confirmed on 11/1/23 at 2:30pm the laboratory failed to maintain an accurate information system.