

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2229796	(X3) Date Survey Completed 09/25/2025
Name of Provider or Supplier Schweiger Dermatology Group	Street Address, City, State 860 First Avenue, Suite 8b, King Of Prussia, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on review of laboratory quality control (QC) records and interview with the General Managers, (GMs) the laboratory failed to retain 4 of 4 months QC records for Hematoxylin and Eosin (H&E) stain for used for microscopic histopathology examinations performed from 09/01/2023 to 12/31/2023. Findings include: 1. On the day of the survey, 09/25/2025 at 09:30 am, the laboratory failed to produce maintenance and function checks for the following equipment used to perform microscopic histopathology examinations for 9 of 9 months from 01/01/2024 to 09/20/2024: 2. The GMs confirmed the above finding on 09/25/2025 around 09:30 a.m. B. Based on lack of documentation and interview of General Managers (GMs), the laboratory failed to retain maintenance and function check records for 9 of 12 months for equipment used for microscopic histopathology examinations performed from 09/01/2024 to 09/30/2024. Findings include: 1. On day of the survey, interview with GMs revealed that record retention is organized differently than previous survey. While gathering the information there were no maintenance records for a 9-month time period from January to September 2024: - Cryostat Temperature Log -Microscope Maintenance Log -Fume Hood Vent Log - Room Temperature Log - Room Humidity Log -Eye Wash Station 2. The laboratory performed 379 microscopic slide examinations(histopathology) in 2024 (CMS-116, estimated annual volume, dated 08/20/2025). 3. During interview with the GMs on 09/25/2025 at 09:30 am, the above findings were confirmed and that the record retention was organized differently than previous surveys.</p>

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's procedure manual, peer review records, and interview with the General Manager (GM), the laboratory failed to ensure that the verification of accuracy for microscopic examinations for histopathology were performed at least twice annually, as required for tests not included in subpart I for 1 of 1 year in 2024. Findings Include: 1. The laboratory's Quality Management Program policy states: " Each lab will participate in a Proficiency Testing program: A Mohs slide exchange with a fellow Mohs surgeon or pathologist performed twice a year, once in every six-month period. Two cases (all slides) will be sent to the reviewing party along with the Proficiency test form." 2. On the day of the survey, 09/25/2025 at 09:35 am, the laboratory could not provide documentation that the verification of accuracy for histopathology slide examinations was performed at least twice annually 1 of 1 year in 2024. 3. The laboratory performed 379 microscopic slide examinations (histopathology) in 2024 (CMS-116, estimated annual volume, dated 08/20/2025). 4. The GM confirmed the findings above on 09/25/2025 around 09:40 am. *** Repeat deficiency***

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on lack of documentation, review of procedure manual and interview with General Supervisors (GMs), the laboratory failed to establish and follow written policies to continually monitor, assess and correct problems identified in the general laboratory systems when microscopic slide examinations (histopathology) were performed from 10/18/2023 to date of survey. Findings include: 1. On the day of the survey 09/25/2025, the laboratory could not provide documentation on the ongoing monitoring and assessments of their general laboratory systems for time periods: - Monthly Laboratory Quality Assurance checklist for October through December 2023. - Monthly Laboratory Quality Assurance checklist for January to August 2024. 2. Procedural manual had signed statement that states: " As of Augst 2024 our Lab Director Dr. Dany stated QA checklist need to be completed every 6 months no longer monthly." 3. The GMs confirmed the above findings on 06/25/2024 at 09:35 am.