Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2072646	12/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology, Pllc - Pathology Lab	65 Broadway, Suite 1606, New York, NY	

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
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 surveyor's review of the laboratory's Quality Assessment (QA) policy, lack of QA records for the calendar years 2019 through November 2021 and an interview with the general supervisor, the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Refer to D6094 FINDINGS: 1. The general supervisor confirmed on December 1, 2021 at approximately 3:15 PM, that the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. 2. The laboratory's QA policy requires a monthly review of all phases of the laboratory's histology testing. a. the laboratory failed to perform and document the monthly QA review for the calendar years 2019, 2020 through November 2021. 3. The laboratory failed to identify and take corrective action for the following issues: a. failure to document the stain quality for the Hematoxylin and Eosin (H&E) and reactivity for the immunostain and special stains for the histology slides.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with

	each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Control (QC) procedure, histopathology QC records and interview with general supervisor, the pathologist /technical supervisor/laboratory director failed to document the positive and negative reactivity and the staining characteristics of the Hematoxylin & Eosin (H&E) stain, special stain and immunostain's each day patient slides were interpreted from April 7, 2021 through August 20, 2021. Refer to D6093 FINDINGS 1. The general supervisor confirmed on December 1, 2021 at approximately 2:00 PM, the pathologist/technical supervisor/laboratory director failed to document the positive and negative reactivity and the staining characteristics for the H&E stain, special stains and immunostain's each day patient slides were interpreted from April 7, 2021 through August 20, 2021 a. the surveyor reviewed the QC log titled "Daily Hematoxylin and Eosin QC Log" sheet, used to record the quality of the stain, had the last date of the evaluation was on April 19,2021 and resumed recording on August 20,/2021. b. the QC Log titled "Technical Evaluation of Tissue Slides" used to record the positive and negative reactivity for the special stain and immunostain's had a date that the evaluation was last performed on April 4, 2021. 2. Approximately 400 patients histopathology slides were read and reported during the above time frame. 3. Monthly review for both H&E QC Log and Tissue Slide was last performed on April 4, 2021.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory QC policies and procedures, histopathology QC records and confirmed in an interview with the general supervisor, the laboratory director/pathologist/technical supervisor failed to ensure that the established histology QC program was maintained to assure the quality of histology testing and identify failures. Refer to D5601
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory QA policies and procedures, QC and QA laboratory records and confirmed in an interview with the general supervisor, the

	laboratory director/pathologist/technical supervisor failed to ensure that the established QA program was maintained to assure the quality of laboratory services and identify failures in quality as they occur. Refer to D5291 and D5601.