Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2072646	05/10/2022
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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory standard operating procedure (SOP) manual and the procedure titled "Vapor Monitoring", lack of air quality reports and an interview with the general laboratory manager, the laboratory failed to maintain adequate space in the accessioning area and laboratory ventilation and air quality in the laboratory area. FINDINGS: 1. The surveyors observed the accessioning area on May 10, 2022, at 10:10 AM, had the received specimen in several containers on the floor next to the three lab aides in the aisle. Surveyors had to step over these containers to walk through the laboratory. 2. The laboratory failed to have adequate space on the accessioning workbench for accessioned specimens, send out specimens and racks grossing specimens to be entered into Novopath laboratory information system (LIS). a. Histology Slide Boxes are stacked in the aisle, by front door, the slide storage room was full. 3. Reviewed the Vapor Monitoring SOP, "states the laboratory monitors staff and/or workstations for formalin and xylene vapor exposure." Monitoring is performed on an annual basis or requested by personnel and the reports are on file in the Histology laboratory. a. No records that this procedure was performed in the laboratory. b. The general laboratory manager on May 10, 2022, at 11:00 AM, stated, "that no previous or current records for vapor monitoring was located." 4. The vapor monitoring procedure using formaldehyde and xylene vapor concentration detection badges to evaluate the air quality for 8 hour period was performed using a vender, which is not the vender listed in the current procedure. a. The badges were sent to the current vender for processing and the report was sent to Schweiger Dermatology Group (SDG) management.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the Competency Assessment policy and an interview with the general laboratory manager, the laboratory failed to establish and follow the Competency Assessment policy. FINDINGS: 1. The laboratory failed to follow their establish competency assessment policy an perform an evaluation for the technical consultant, general laboratory manager a. No documentation was available for review at this survey.
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 review of the Quality Assessment (QA) policy, lack of QA documentation, the laboratory failed to follow and maintain their established QA policy. FINDINGS: The QA policy stated, "that the quality system must be designed to assess and continuously improve the delivery of services to meet the needs of patients and all clinical personnel responsible for patient care. And that the quality manual will contain documentation of ongoing efforts by the Quality Management System Committee to fulfill the quality system elements including agenda, minutes to the meetings and monthly QA checklist." a. No documentation was available currently for surveyors to review. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON DECEMBER 1, 2021.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the QA policy, lack of QA/corrective action documentation, the laboratory failed to implement the plan of correction from the survey conducted December 1, 2021 and review the effectiveness of corrective actions taken to address problems and issues, revision of policies and procedures to prevent recurrence of problems. Refer to D5921 and D6094

D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of the laboratory's SOP manual, review of ten test requisitions/5 each for both pathologist and an interview with the laboratory director, the laboratory failed to establish a procedure to verify the information and orders handwritten by the pathologist(s) on the test requisition, when it's transcribed into the Novopath LIS system. FINDINGS: The pathologist writes orders randomly on the test and not in a uniform space resulting in orders that can be unclear. a. The test requisition is sent back to the lab aide to transcribe information and orders into Novopath LIS system. b. The laboratory director confirmed on May 10, 2022, at 2:00 PM that the SOP manual did not include a procedure to verify the information is entered into the Novopath system accurately.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory SOP manual and an interview with the general laboratory manager, the laboratory director failed to review, sign, date and implement the laboratory manual on August 11, 2021. FINDINGS: 1. The current laboratory director replaced the previous laboratory director on August 11, 2021. The laboratory director only signed one of the procedures titled "Scope of Service" on December 21, 2021. 2. The general laboratory manager confirmed on May 10, 2022, at 10:45 AM, the laboratory director failed to review, sign, date and implemented laboratory manual.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's SOP manual, direct observation and an interview with general laboratory manager, technical consultant and laboratory director, the director failed to provide overall management for all phases of histology testing. Refer to D6083, D6084, D6094 D6106, D6102, D6103, D6107, D6120 FINDINGS: The laboratory director failed to ensure: 1. That the plan of correction from the survey conducted on December 1, 2021, was maintained. 2. That the physical and environmental conditions of the laboratory; Refer to D6083, 3. That the physical and

	environmental conditions provide a safe environment in which employees; Refer to D6084, 4. That failures were identified, and remedial action taken in the QA SOP, Refer to D6094, 5. That all personnel receive the appropriate training for the type and complexity of the tasks they perform, Refer to D6102, 6. Those policies and procedures were established to monitor personnel that perform all three phases of laboratory testing, Refer to D6103, 7. That the laboratory's SOP manual was approved and available to all personnel, Refer to D6106, 8. That job description, responsibilities and duties for the lab aides, general laboratory manager, technical consultant and the transcriptionist were specified in writing, Refer to D6107, 9. That the staff were not adequately trained for their duties, Refer to D6120.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the general laboratory manager and technical consultant, the laboratory director failed to ensure that the physical and environmental conditions of the laboratory are suitable for the testing personnel. Refer to D3001
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on review of the SOP for Vapor Monitoring, lack of air quality reports and an interview with the general laboratory manager and technical consultant, the laboratory director failed to ensure that the physical and environmental conditions provide a safe environment for the laboratory personnel. Refer to D3001
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 review of the laboratory's QA policy, lack of QA documentation review and an interview with the general laboratory manager, the laboratory director failed to maintain the established QA policy. Refer to D5291 THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON DECEMBER 1, 2021.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the job descriptions policy and competency assessment policy and an interview with the general laboratory manager, the laboratory director failed to ensure that, all personnel receive the appropriate training for the type and complexity of the tasks they perform. Refer to D5209 and D5291
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the job descriptions policy and competency assessment policy and an interview with the general laboratory manager, the laboratory director failed to define the duties and job description for the lab aides, transcriptionist, general laboratory manager and technical consultant and provide training for those tasks that are performed.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and an interview with the general laboratory manager, the laboratory director failed to provide an approved manual to all personnel responsible for all phases of histology testing. Refer to D5407
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

	supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, lack of job description documentation and an interview with the laboratory director, the laboratory director failed to specify, in writing, job description, responsibilities and duties for the lab aides, general laboratory manager, technical consultant and the transcriptionist.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, staff interviews, lack of job description records, and an interview with the laboratory director, the laboratory director, acting as the technical supervisor, failed to identify training needs and assuring that the lab aides transcribing the dictation for the pathologist receives training for the type and complexity of the laboratory services performed. Refer to D6102 and D6103