Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2072646	09/12/2022
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the bottle of Xylene and interview with the general supervisor, the laboratory failed to label the prepared Xylene with the required information. FINDINGS: Xylene Prepared 10-29-19 exp 6/1/21/was prepared by TH, did not have the concentration and the storage range for room temp on the label. a. The manufacturer requires a room temperature of 15-30 C for the storage of the Xylene.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the Hematoxylin stain in the laboratory's storage area, inks for histology specimens in the grossing area and interview with the general supervisor, the laboratory failed to review reagent, solutions stains and inks for expired dates. FINDINGS: The surveyor observed the following: Hematoxylin stain

	and inks used for histology specimens: Hematoxylin Stain- Surgipath- #115068 exp 8 /31/22- 2 bottles 500 ml Black Ink- 1 bottle #065705 exp 4/20 Yellow Ink-1 bottle #065586 exp 4/20
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review and observation of test requisition, lack of a written procedure for retention of both original and amended reports, and interview with the general supervisor, the laboratory failed to establish a procedure for differentiating between original report and amended report and retention of the original report and amended report. FINDINGS: 1. Pathologist #1 recorded the result date on her original report but modifies the date on the orginal report to reflect the amended report date. a. SD22-34348 Original 6/16/22 amended 6/17/22 b. SD22-36618 Original 6/23/22 amended on 6/27/22 2. Laboratory director/pathologist performed it correctly that when an amended report was generated only the amended information was dated with the amended date, leaving the original date reported and electronic signature dates constant with the original report a. SD22-32082 Original 6/3/22 amended 6/13/22 b. SD22-32582 Original 6/10/2 amended 6/15/22 c. SD21-53802 Original 10/6/21 amended on 11/12/21 3. The general supervisor confirmed on September 12, 2022, at approximately 2:30 PM that the laboratory failed to establish a procedure for differentiating between original report and amended report and retention of the original report and amended report. The procdure must define th following: a. Time frame as to when the corrected reports are sent to the authorized person. b. Retention of the original report and corrected reports. c. Maintain duplicates of the original report, as well as the corrected report d. Ensure that incorrect original results are not reissued.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review and observation of test requisition, lack of a written procedure for retention of both original and amended reports and interview with the general

	supervisor, the laboratory director failed to ensure that the histology reports differentiate between original report and amended report and retention of the original report and amended report. Refer to D5821.