Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0868562	(X3) Date Survey Completed 10/05/2023
Name of Provider or Supplier Schweiger Dermatology Pllc	**Street Address, City, State** 229 Seventh Street Suite 105, Garden City, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on direct observations as well as lack of procedures and records, the laboratory failed to draft, approve, and maintain instructions for removal of expired reagents from inventory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on October 5, 2023, at approximately 10:45 A.M. that the current Schweiger Dermatology, PLLC standard operating procedures did not include written, approved instructions for removal from inventory expired reagents utilized for processing of patient specimens.

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 direct observations and interview with the Office Manager (OM), the laboratory failed to document aliquot bottle dye name, lot number, expiration date, and storage requirements for blue, green, red, black, and yellow dyes in use at the time of the survey. FINDINGS: 1. Confirmed findings by interview with the OM on October 5, 2023, at approximately 10:45 A.M.
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 direct observations and interview with the OM, the laboratory failed to remove from inventory expired reagents in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on October 5, 2023, at approximately 10:45 A.M. the following reagents and processing materials were not removed from inventory: a. One bottle of blue dye; expiration date: September 1, 2020, lot #070030. b. One bottle of green dye; expiration date: September 1, 2020, lot #070026. c. One bottle of red dye; expiration date: October 1, 2020, lot #070411. d. One bottle of black dye; expiration date: September 1, 2020, lot #069204. e. One bottle of yellow dye, expiration date: October 1, 2020, lot#070421. 2. Approximately 948 patients were tested in calendar year 2022. 3. Confirmed findings by interview with the OM on October 5, 2023, at approximately 10:45 A.M.