Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1088556	10/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
New York Cosmetic Skin & Laser Surgery Center	901 Stewart Ave, Suite 240, 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 18, 2023, at approximately 11:00 A.M. that the current standard operating procedures did not include written, approved instructions for removal from inventory expired reagents utilized for processing of patient specimens.

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 lab director, the laboratory failed to remove from inventory expired reagents located in the Mohs processing laboratory. FINDINGS: 1. The observations in the Mohs processing laboratory confirmed on October 18, 2023, at approximately 10:45 A.M. the following reagents and patient specimen processing materials were not removed from inventory: a. Three bottles of Tissue-Tek; expiration date: October 31, 2022, lot #1481-00. b. Two bottles of Xero Freezing Medium; expiration date: May 13, 2022, lot #1L6. 2. Approximately 135 patients were tested in the calendar year 2022. 3. Confirmed findings by interview with the Laboratory Director (LD) on October 18, 2023, at approximately 11:00 A.M.