Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1088553	10/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
New York Cosmetic Skin & Laser Surgery Center	121 East 60th Street - Suite 8ab, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the billing manager, the laboratory failed to document room and cryostat temperatures as well as humidity on all days of slide processing and examination. Findings: 1. The cryostat manufacturer's requirements specified a temperature range of -20C - -30C. 2. The laboratory maintained a log for documenting room temperature and humidity. 3. No cryostat, room temperatures, and humidity were recorded for: a. October 19, 2023. b. September 21, 2023. c. June 29, 2023. d. On each day, five patient cases were evaluated. 4. Confirmed findings by interview with the billing manager on October 31, 2023, at 11:30 A.M.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, the quality control (QC) log, and interview with the billing manager, the laboratory failed to document H&E stain reactivity for each day of use. Findings: 1. The procedure manual indicated that on each day that patient slides were evaluated, the first slide assessed would be a QC slide for H&E stain reactivity. 2. The laboratory maintained a log documenting H&E stain reactivity. 3. QC slides were present in the processing area. 4. No H&E stain reactivity was recorded on: a. September 21, 2023. b. June 29, 2023. c. December 15, 2022. d. A total of seventeen patient cases were evaluated on the three respective days. 5. Confirmed findings by interview with the billing manager on October 31, 2023, at 11:30 A.M.