Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0685951	09/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Eastside Dermatology Services Pc	317 East 34th Street 11th Floor, Suite A, 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
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 lack of thermometer calibration procedures and records, and interviews with the (Chief Operating Officer) COO and nursing manager, the laboratory failed to retain approved instructions for the calibration of thermometers. FINDINGS: 1. The nursing manger and COO confirmed on September 6, 2023, at approximately 11:00 A. M. that the American College of Mohs Surgery (ACMS) Manual of Frozen Section Processing for Mohs Micrographic Surgery and Maintenance Log did not include written, approved instructions for performing calibrations of thermometers. 2. The

	nursing manager and COO confirmed on September 6, 2023, at approximately 11:00 A.M. that the laboratory did not retain thermometer calibration certificates and the manufacturer's instructions for calibration of thermometers.
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 ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery and interviews with the nursing manager and COO, the laboratory failed to document procedure approval and date of approval by the current laboratory director. FINDINGS: 1. The nursing manger and COO confirmed on September 6, 2023, at approximately 1:00 P.M. that the ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery did not include documented approval and date of approval by the laboratory director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observations, review of the Material Safety Data Sheets (MSDS), reagent manufacturer's storage requirements, and interviews with the nursing manager, COO, and Testing Person (TP) #1, the laboratory failed to properly store flammable reagents in the Mohs processing laboratory as required by the MSDS and ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery. FINDINGS: 1. The surveyors' observations in the Mohs processing laboratory confirmed on September 6, 2023, at approximately 10:15 A.M. the following reagents and processing materials were not properly stored in the flammable materials storage cabinet as required by the MSDS and the ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery: a. EDM3 Acetone lot: 1313 was stored in a lower cabinet in the Mohs processing laboratory. b. Histo-Clear lot: 05-22-16 was stored in a lower cabinet in the Mohs processing laboratory. c. Eosin Working Solution lot: G128-02 was stored in a lower cabinet in the Mohs processing laboratory. d. Toluidine Blue lot: 11241 was stored in an overhead cabinet in the Mohs processing laboratory. e. Several units of 70% Isopropanol Ref: 112-7067 were stored in an overhead cabinet beside the lab's spill kit in the Mohs processing laboratory. 2. It was noted that the respective reagents and processing materials were properly stored in the flammable materials storage cabinet during the survey in partial satisfaction of this requirement.
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 direct observations, lack of room temperature records, lack of approved standard operating procedures, and an interview with the nursing manager, COO, and TP #1, the laboratory failed to install a room temperature thermometer for the measurement of the temperatures in the Mohs processing laboratory. FINDINGS: 1. The nursing manager, COO, and TP #1 confirmed on September 6, 2023, at approximately 10:00 A.M. that the Mohs laboratory did not include a thermometer for monitoring room temperatures where reagents, stains, and inking materials were stored. a. It was noted that the Acu-Rite thermometer model: 00619HDSBA3 was temporarily installed in the Mohs laboratory during the survey in partial satisfaction of this requirement. 2. The nursing manager and COO confirmed on September 6, 2023, at approximately 11:30 A.M. that the Mohs laboratory standard operating procedures did not include written, approved instructions for monitoring and documenting room temperatures where reagents, stains, and inking materials were stored. a. It was noted that a temperature log sheet and written instructions for monitoring and documenting Mohs laboratory room temperatures were drafted during the survey in partial satisfaction of this requirement.
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 TP #1, the laboratory failed to remove from inventory expired reagents in the Mohs processing laboratory as required by the ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on September 6, 2023, at approximately 10:15 A.M. the following reagents and processing materials were not removed from inventory as required by the ACMS Manual of Frozen Section Processing for Mohs Micrographic Surgery: a. Toluidine Blue lot: 11241 expiration: June 30, 2022, was stored in an overhead cabinet in the Mohs processing laboratory. b. Eosin-Y Working Solution expiration: February 28, 2023, was stored in the flammable materials storage cabinet in the Mohs processing laboratory. c. Gill 3 Hematoxylin expiration: September 30, 2021, was stored in a lower cabinet in the Mohs processing laboratory. d. It was noted that the respective reagents and processing materials were removed from the Mohs processing laboratory inventory during the survey in partial satisfaction of this requirement. 2. The TP #1 confirmed on September 6, 2023, at approximately 10:30 A.M. that the respective expired reagents and processing materials were not utilized for patient specimen processing.