Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1105108	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Long Island Medical & Cosmetic Dermatology Pc	755 Park Ave, Suite 500, Huntington, 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 surveyor review of the pathology laboratory's procedure manual and interview with the laboratory consultant, the laboratory failed to establish written procedures for: 1. A procedure describing laboratory's turnaround time for the Dermatopathology from sample collection to processing and to when final diagnosis is determined by the pathologist and entered into the lab computer system. 2. A procedure for acceptance of staining quality of the Hematoxylin & Eosin (H&E) stain, special stain and Immunohistochemistry (IHC) stain on each day of reading.

D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor review of the Quality Control (QC) documentation for Dermatophyte Media (DTM) and interview with the laboratory consultant and the office manager, the laboratory failed to perform QC on each new shipment/lot number of DTM used for fungal cultures. Findings: 1. The documentation of QC was not available for 6 boxes of DTM lot number D1270-0518, expiration date 7/5/2020. 2. The laboratory consultant and the office manager confirmed on August 6, 2019 at approximately 11:00 AM that the laboratory failed to use known positive and known negative organisms to test the reactivity for each new box of DTM in calendar year 2018. 3. Approximately 60 patient samples were tested and reported for fungal culture in calendar year 2018 using the above lot number of DTM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory records, and confirmed in an interview with the laboratory consultant, the Laboratory Director failed to ensure the laboratory quality assurance policies were maintained. Findings: 1. The laboratory has established a policy to document on each day of on-site reading, the pathologist reading sessions on a logsheet entitled "Pathologist Sign-In Log". The Pathologist Sign-In Log includes date, time in, time out, and the pathologist initial. 2. On August 6, 2019 at approximately 11:00 AM the laboratory consultant confirmed that on July 28, 2019 the pathologist read 71 slides and on August 3, 2019 the pathologist read 57 slides. There was no record of on-site reading on the Pathologist Sign-In Log on the above dates. The laboratory must follow own established policy.