Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0154289	11/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic Dermatologic Associates Llp	266 Merrick Road, Suite 201, Lynbrook, 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
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 office manager, the laboratory failed to perform QC on each new shipment/lot number of DTM used for fungal cultures in calendar year 2018. Findings: 1. The office manager confirmed on November 4, 2019 at approximately 10:00 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. 2. Approximately 50 patient samples were tested and reported for fungal culture in calendar year 2018.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the

	manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor review of QC records for dermatophyte media (DTM) used to perform fungal testing and an interview with the office manager, the laboratory failed to document the physical characteristics and failed to perform sterility check on DTM in calendar year 2018. FINDINGS: 1. On November 4, 2019 at approximately 10:00 AM, the office manager confirmed that the laboratory failed to perform physical characteristics and to perform the sterility check for each new batch (shipment) or lot number of DTM in calendar year 2018. 2. Approximately 50 patient samples were tested and reported for fungal culture in calendar year 2018.