Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1046621	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
University Of South Florida Dermatology	13330 Laurel Dr 6th Fl, Tampa, FL	

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 observations, record review, and interview with the Laboratory Director the laboratory failed to document the temperature of the location where DTM (Dermatophyte test mediums) cultures were set up for 2 out of 2 years reviewed (2017-2018). Findings Included: During a tour on 02/22/19 at 11:30 AM of the location in which DTM cultures were set up (a cabinet in the Physician consult room), it was observed that no thermometer present. Review of the manufacturer's instructions for the DTM cultures revealed that the cultures must be incubated at 22-30 degrees Celsius. During an interview on 02/22/19 at 11:30 AM, the Laboratory Director confirmed that the temperature of the cabinet where the DTM cultures were stored after set up was not being monitored.
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 record review and interview with the Laboratory Director the laboratory failed to document the physical characteristics of the DTM (Dermatophyte Test Medium), the ability for the DTM medium's sterility and ability to support growth for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of the DTM records revealed that the physical characteristics were not recorded for each lot or shipment in 2017 and 2018. The DTM records also revealed that each lot or shipment did not have documentation of sterility testing (negative control) and the ability to support growth (positive control) for both 2017 and 2018. During an interview on 02 /22/19 at 11:30 AM the Laboratory Director confirmed that the physical characteristics were not recorded nor were the sterility and ability to support growth documented in 2017 and 2018.