Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2051559	08/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mary A Yurko Md Dermatology Pllc	833 Michigan Street Ne, Suite 102, Grand Rapids, MI	

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
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 (LD), the laboratory failed to perform and document media checks for the "ACU-DTM Dermatophyte Test Medium (DTM)" with each new batch, lot, or shipment for the ability to support growth of yeast for 2 (August 2017 to August 2019) of 2 years. Findings include: 1. A record review of "ACU-DTM (Dermatophyte Test Medium) Directions for Use" in the package insert exposed a section stating, "CLIA requires the end user to perform a minimum of a positive and negative control on each new lot or batch purchased." The table indicated the microorganisms to use for quality control were, "Trichophyton mentagrophyte, E. coli, and Candida albicans." 2. When requested by the surveyor on 8/12/19 at 2:40 pm, the laboratory did not provide records of performing yeast controls on the DTM. 3. An interview on 8/12/19 at 2:40 pm with the LD confirmed media checks for the ability to support growth of yeast had not been performed.