Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0701455	03/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Golden State Dermatology	1324 Nelson Ave Ste B, Modesto, CA	

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 observation of DTM vials (Dermatophyte Test Medium; Accuderm), review of laboratory records for fungal cultures, the lack of laboratory QC records, and interview with laboratory personnel, the laboratory failed to perform and document quality control procedures to check each lot # and shipment of DTM for contamination, discoloration, and its ability to support growth of dermatophyte(s) and select or inhibit other specific organisms. Findings included: a. Vials of DTM lot # D-1300-1118, expiration 2020-11-01, were available for use. b. The laboratory was unable to provide for review QC records for the aforementioned lot #. c. A laboratory assistant affirmed (3/07/19) the aforementioned lack of QC records; and thus, the failure to perform and document QC activities to inspect each lot number of DTM for contamination, discoloration, and it's ability to support growth of dermatophytes. d. The reliability and quality of Negative DTM fungal culture results could not be assured. Based on the stated annual test volume (CMS116, 3/07/2019), the laboratory reported approximately 175 DTM cultures annually. .