Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0686425	02/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Greenbrae Dermatology Amc	501 Sir Francis Drake Blvd, Ste 200, Greenbrae, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of fungal culture and vials of expired DTM (Dermatophyte Test Medium), review of test records, and interview with Testing Person-1, it was determined that the laboratory used DTM past their expiration date. Findings included: a. A fungal culture dated 2/15/19 was inoculated onto DTM lot # D1161-1215, expiration date 12/17/2017. b. Laboratory test records revealed only DTM expired 12/17/17 were available for use throughout 2018 to 2/25/19, date of inspection. c. Testing Person-1 affirmed (2/25/19 at 1:00pm) the aforementioned observations. d. The reliability and quality of fungal cultures results could not be assured when expired media was used. Based on review of laboratory records, the laboratory performed more than 5 fungal cultures in 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 observation of DTM, review of the log book for fungal cultures, the lack of QC records, and interview with Testing Person-1, the laboratory failed to check each lot number of DTM for its ability to support growth of dermatophytes and produce appropriate biochemical response. Findings included: a. DTM lot # D1161-1251 was available for use and had been inoculated for a fungal culture on 2/15/19. b. The laboratory was unable to provide for review QC records checking each lot number for its ability to support growth of dermatophytes in 2017 to 2019. c. Testing Person-1 affirmed (2/25/19 at 1:00pm) the aforementioned lack of QC for each lot # of DTM used. d. The reliability and quality of negative fungal cultures could not be assured when the DTM had not been checked for it's ability to support growth of dermatophytes.