Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2042650	11/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Dermatology	3736 Atlantic Ave Ste 101, Long Beach, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel reports (CMS-209, LAB116) and laboratory records, the lack of laboratory documents, and interview with laboratory personnel, the laboratory failed to at least twice annually verify the accuracy of histopathology fresh frozen biopsies and Mohs procedures. Findings include: a. The laboratory personnel reports included testing person for histopathology procedures. b. Laboratory records documented Fresh Frozen Biopsies (FFB) and Mohs procedures. c. The laboratory was unable to provide for review documents verifying the accuracy of the pathology reports for the FFB and the final stage of clearing for the Mohs procedures performed in 2017. d. A laboratory assistant affirmed (11/14/18) the lack of aforementioned documents; and thus, the failure to at least twice annually verify the accuracy of testing in 2017. e. The relaibility and quality of histopathology procedures performed in 2017 could not be assured. Based on the stated estimated annual test volume, the laboratory performed approximately 300 in 2017. . .
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; Troy Biologicals, Inc), review of laboratory records for fungal cultures, the lack of laboratory records, and interview with laboratory personnel, the laboratory failed to perform positive and negative quality controls to check each batch of media for its ability to support growth of dermatophyte(s) and select or inhibit other specific organisms; and document all procedures according to manufacturer's instructions. Findings include: a. The laboratory utilized DTM to culture for dermatophytes. A culture dated 10/24/18 was inoculated into a vial from lot #1818312, expiration date 7/02/19. Other noninoculated vials for current use were lot #1819109, expiration date 7/10/19. b. The laboratory was unable to provide for review QC records for all previous lot numbers used in 2017-2018 including checking each lot number of media for it's ability to support the growth of dermatophytes and inhibit other organisms. c. The laboratory was unable to provide for review records documenting quality per manufacturer's instructions: 1) Inspect plates for expiration date, drying, cracking, discoloration, microbial contamination or any other signs of deterioration. 2) Record the lot numbers and expiration dates. d. A laboratory person affirmed (11/14/18) the aforementioned lack of QC records; and thus, the failure to keep track of Lot numbers received with Expiration Date, perform and document QC activities to inspect each lot number of DTM for sterility, and determine it's ability to support growth of dermatophytes. e. The reliability and quality of Negative DTM results could not be assured. Based on the estimated annual test volume, the laboratory reported approximately 90 DTM cultures annually. .
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the cumulative nature of deficiencies cited, the Laboratory Director is herein cited for deficient practice in ensuring that quality control programs are established and maintained to assure quality and identify failures as they occur. Findings include: a. The laboratory failed to maintain QC. See D5477. b. The laboratory failed to at least twice annually verify the accuracy of testing. See D5217.