Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0603818	01/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bruce R Carlton Md Inc	2101 Vale Rd, Ste 301, San Pablo, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of culture media for dermatophyte (fungal) cultures, the lack of laboratory written procedures and quality control documents, and interview with laboratory personnel and the Laboratory Director, the laboratory failed to have a written procedure addressing culture media. Findings include: a. The laboratory used DTM (Dermatophyte Test Medium) and Sabouraud Dextrose media to culture for dermatophytes and yeast. b. The laboratory was unable to provide for review written laboratory procedure addressing the use, quality assurance, and quality control for the media. c. The laboratory was unable to provide documents for quality assurance and quality control. See D5417 and D5477. d. Laboratory personnel and the Laboratory Director (Testing Person, Technical Consultant) affirmed the failure to establish a written laboratory procedure for the DTM and Sab-Dex culture media. .
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 expired Sabouraud Dextrose media in use, review of patients test records, and interview with laboratory personnel and the Testing Person (Laboratory Director), the laboratory used expired culture media. Fingings include: a. For Sab-Dex cultures in progress, 3 out of 5 vials inoculated in January 2018 were Lot # S-54-0615 with expiration date 6/22/17. b. Laboratory personnel and the Testing Person (Laboratory Director) affirmed the aforementioned use of expired culture media. c. The reliability and quality of the expired culture media used could not be assured for patients tested as follows: Date inoculated Sab-Dex Culture ID ---------- ---------- 1/12/18 ES 1/15/18 RM 1/17/18 NP d. Due to the lack of documentation it could not be determined if the expired media was used for other previous cultures. Based on the stated estimated annual test volume, the laboratory reported approximately 9 mycology tests each month during the timeframe June 2017 to January 2018, including culture and direct microscopic examination method (KOH). .
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 culture media in use, the lack of laboratory quality control documents, and interview with labortory personnel and the Testing Person (Laboratory Director, Technical Consultant), the laboratory failed to document all quality control and quality assurance procedures performed. Findings include: a. Cultures in progress included the following Lot numbers of media: Date in use ID Lot # Expiration ---------- ------- ---------- ---------- 12/13/17 RS D-1206-1116 2018-11-15 1/15/18 MM D-1198-0916 2018-09-07 1/19/18 RR D-1206-1116 2018-11-15 b. The laboratory was unable to provide for review quality assurance documents verifying the physical conditions of each Lot number of DTM upon receipt for acceptable color, sterility, and absence of breakage. c. The laboratory was unable to provide for review quality control documents checking each lot number of media for its ability to support growth of dermatophyte. d. Laboratory personnel and the Testing Person (Laboratory Director) affirmed the aforementioned failure to document all quality assurance and quality control procedures performed. e. Based on the stated estimated annual test volume, the laboratory performed approximately 110 mycology tests annually, including culture and microscopic examination (KOH).