Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1073390	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Peterson Dermatology	305 First Street West, Vidalia, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August,16 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the procedure manuals and staff interview, the laboratory was not enrolled in a proficiency testing(PT) program. Findings: 1. Review of the procedure for Dermatophyte Test Medium (DTM), failed to mention that PT was being performed. 2. Interview with the LD and staff #3 (CMS 209 form), on August 18, 2018, at approximately 2:30 pm in the lab, confirmed that the laboratory was not performing PT for the DTM procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure for Dermatophyte Test Medium(DTM), and staff interview, the procedure failed to list that Proficiency Testing (PT), must be performed. Also, in the procedure for Quality Control (QC), the procedure failed to list that the media must be verified by plating a positive and a negative organism to verify the media being selective for growth. Findings: 1. Review of the procedure for DTM, the procedure failed to state that PT must be performed, and QC of the media consist of plating the media with a positive and negative organism to confirm growth for the selective media. 2. Interiew with the LD and staff #3 (CMS 209 form) on August 18, 2018, at approximately 2:45 pm in the lab, confirmed that the procedure did not PT as part of the procedure, and that they were only performing visual QC on the DTM media.
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 review of the Dermatophyte Test Mediam (DTM) documents, and staff interview, the laboratory was not performing Quality Control(QC) on the DTM media used for testing. Findings: 1. Review of the DTM documents did not show the results for DTM media QC for 2017, and 2018. 2. Interview with staff #3, and the Laboratory Director, on 8/16/2018, at approximately 2:15 pm in the Histology Lab, confirmed that the laboratory was unaware that QC had to be performed for the DTM media, and that QC was not performed for 2017 and 2018, to date of the survey.