Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0705493	09/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Peachtree Dermatology Associates	371 East Paces Ferry, Ne, Suite 900, Atlanta, 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 September 19, 2019. 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 documents presented to review and staff interviews,the laboratory failed to enroll and participate in Proficiency Testing (PT). Findings include: 1. Review of documents presented revealed the laboratory was not enrolled in PT for the subspecialty of mycology, dermatophytic fungi (DTM). 2. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:38 AM in the front office manager's office, confirmed the lab was not participating in PT.
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 document review and staff interviews, the laboratory failed to verify the accuracy of testing at least twice per year for provider performed microscopic exams (PPM). Findings include: 1. Review of documents presented revealed the laboratory was not verifying the accuracy of tests in the subspecialties of mycology and parasitology (Peer reviews). 2. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:38 AM in the front office manager's office, confirmed the lab was not participating in verifying the accuracy of PPM tests.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records presented and staff interviews, the laboratory failed to establish and follow written policies and procedures for ongoing quality assessment (QA). Findings include: 1. Review of the laboratory records presented revealed the lack of written policies and procedures for ongoing QA program. 2. Review of the laboratory's records revealed no documentation of monitors to evaluate the overall quality of testing performed. 3. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:38 AM in the front office manager's office, confirmed the lab did not have a QA program.
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 review of the procedure manual (SOP) and staff interviews, the laboratory failed to have written procedures for all tests performed. Findings include: 1. Review of the SOP revealed the lack of procedure for potassium hydroxide (KOH) prep and scabies wet prep. 2.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved

	proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on documents presented for review and staff interviews,the laboratory director (LD) failed to ensure the laboratory was enrolled and participated in Proficiency Testing (PT). Findings include: 1. Review of documents presented revealed the laboratory was not enrolled in PT for the subspecialty of mycology, dermatophytic fungi (DTM). 2. Interviews with the clinic manager and the front office manager on 9 /19/19 at 10:38 AM in the front office manager's office, confirmed the lab was not participating in PT.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory records, procedure manual (SOP), and staff interviews, the laboratory director failed to ensure the personnel receive the appropriate training for the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Review of the SOP revealed the lack of a written policy to train and evaluate employees prior to performing patient testing. 2. Review of the laboratory's records revealed no documentation of training for 4 of 4 testing personnel listed on the CMS 209 form. 3. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:30 AM in the front office manager's office, confirmed the lab did not have the aforementioned policy or documentation.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interviews, the technical consultant (laboratory director) failed to evaluate and document the competency of testing personnel at least semiannually during the first year of testing patient specimens. Findings include: 1. Review of the laboratory's records revealed no documentation of semiannual competency for 4 of 4 testing personnel listed on the

	CMS 209 form. 2. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:30 AM in the front office manager's office, confirmed the lab did not have the aforementioned documentation.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interviews, the technical consultant (laboratory director) failed to evaluate and document the competency of testing personnel at least annually after the first year. Findings include: 1. Review of the laboratory's records revealed no documentation of annual competency for 4 of 4 testing personnel listed on the CMS 209 form. 2. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:30 AM in the front office manager's office, confirmed the lab did not have the aforementioned documentation.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory records and staff interviews, the technical consultant (laboratory director) failed to evaluate and document the competency of testing personnel at least semiannually during the first year of testing patient specimens. Findings include: 1. Review of the laboratory's records revealed no documentation of semiannual competency for 4 of 4 testing personnel listed on the CMS 209 form. 2. Interviews with the clinic manager and the front office manager on 9/19/19 at 10:30 AM in the front office manager's office, confirmed the lab did not have the aforementioned documentation.