Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0685301	11/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Greensboro Dermatology Associates, Pa	2704 St Jude Street, Greensboro, NC	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 MLE (Medical Laboratory Evaluation) proficiency testing records and review of the laboratory's policies and procedures 11/6/19, the laboratory failed to document evaluation of all ungraded proficiency testing results. Review of 2018 and 2019 MLE proficiency testing records revealed: 1. 4 of 5 DTM (dermatophyte test medium) samples were ungraded on the 2018 M3 test event; 2. 2 of 5 DTM samples were ungraded on the 2019 M1 test event. There was no documentation available to indicate that the ungraded results were evaluated to determine whether they were acceptable or whether corrective action was required. Review of the laboratory's "Proficiency Testing" policy revealed the policy did not include a procedure for review of proficiency testing results, including how to evaluate results that are not graded by the proficiency testing company and corrective actions to take for unacceptable results.
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 review of manufacturer's instructions and observation 11/6/19, the

	laboratory failed to discard media that exceeded its expiration date. Manufacturer's instructions for the HealthLink DTM (Dermatophyte Test Medium) state "...VI. STORAGE/SHELF LIFE ... Product that has exceeded the assigned expiration date noted on the label should not be used. ..." During a tour of the laboratory at approximately 2:00 p.m., the surveyor observed: 1. 1 patient fungal culture set up 11/6 /19 on expired DTM media (lot #1810902, expiration date 4/19/19). 3 unused vials of the same lot number were in a drawer in the nurses' station, available for use. 2. 1 box of HealthLink DTM (lot #1818311, expiration date 7/2/19) in the nurses' station refrigerator, available for use.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2018 and 2019 quality control and patient logs 11/6/19, the laboratory failed to ensure DTM (dermatophyte test medium) quality control results were acceptable prior to reporting patient test results. Findings: 1. The laboratory's "DTM Quality Control" procedure states "... 12. If results are not satisfactory, the test must be repeated." Review of 2018 and 2019 DTM quality control logs revealed quality control testing for DTM lot #1725712 (expiration date 9/14/18) was set up on 2/19/18. The positive control failed, so the testing was repeated 3/20/18. The positive control failed again, so the testing was repeated 6/29/18. Acceptable quality control results were read and documented 7 /13/18. The lot number of DTM media in use prior to the failed quality control was lot #1712114 which expired 5/1/18. Review of 2018 and 2019 patient logs revealed 4 patient DTM fungal cultures were set up between 5/1/18 (expiration date of previous lot number) and 7/13/18 (the date that acceptable quality control results were achieved): a. patient #101993 set up 6/1/18; b. patient #533787 set up 6/29/18; c. patient #46022 set up 7/11/18; d. patient #26604 set up 7/12/18. It was unclear from the records available which lot number of media was used to perform the patient tests. 2. Review of 2018 and 2019 DTM quality control logs revealed no quality control testing for DTM lot #1810902 (expiration date 4/19/19) and DTM lot #1818311 (expiration date 7/2/19). 4 patient DTM fungal cultures (#536653, #108474, #105555, #72950) were performed between 5/1/19 and 7/2/19, but it was unclear which lot number of DTM media was used to perform the tests.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2018 and 2019 patient logs 11/6/19, testing personnel failed to follow the laboratory's procedure for performing Tzanck smears. The laboratory's "Proficiency Testing" procedure

	states "... TZANCK: There is no outside proficiency slides available for this test so, all TZANCK slides will be read by two physicians. ..." Review of 2018 and 2019 patient logs revealed the logs included the following statement "ALL TZANCKS REQUIRE A DOUBLE PHYSICIAN READING". Review of 2018 and 2019 patient logs revealed the laboratory performed Tzanck smears on 3 patients during 2018 and 2 patients during 2019 from January through October. 3 of the 5 patient Tzanck smears performed were read by only one provider.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of the laboratory's written quality assessment plan and review of 2018 and 2019 laboratory records, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program to assure the quality of laboratory services provided. Findings: 1. The quality assessment plan was not specific for the laboratory and had not been updated to include activities performed to evaluate the preanalytic, analytic, and postanalytic systems, including corrective action to take if problems are identified. 2. The quality assessment plan failed to ensure evaluation and corrective action for ungraded proficiency testing results (see D5211). 3. The quality assessment plan failed to identify problems with DTM (dermatophyte test medium) fungal culture testing identified during the survey (see D5417, D5481).