

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0685301	(X3) Date Survey Completed 01/23/2023
Name of Provider or Supplier Greensboro Dermatology Associates, Pa	Street Address, City, State 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2021, 2022, and 2023 DTM (dermatophyte test medium) patient records and interview with the clinical manager 1/23/23, the laboratory failed to discard expired DTM media and the media was used for patient testing. Review of DTM patient records revealed: 1. DTM lot #X15-477938 with expiration date 7/21/21 was used to test patient #549312, set up 7/28/21. 2. DTM lot #X15-482919 with expiration date 10/10/21 was used to test the following patients: a. patient #545194, set up 10/27/21; b. patient #9958, set up 11/9/21; c. patient #32671, set up 2/23/22; d. patient #553580, set up 7/18/22. During interview at approximately 1:25 p.m., the clinical manager stated the DTM lot number might not have been documented correctly on the patient log. She stated the new lot number of DTM (lot #X15-491957, expiration date 3/9/22) should have been used for patients set up on 10/27/21, 11/9/21, and 2/23/22.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's plan of correction for the deficiencies cited during the 11/6/19 recertification survey and review of 2020, 2021, and 2022 MLE (Medical Laboratory Evaluation) proficiency testing records 1/23/23, the laboratory director failed to ensure evaluation of all ungraded and unacceptable proficiency testing results for 6 of 9 proficiency testing events reviewed to ensure all necessary corrective action was taken and documented as required. Findings: Review of the "Proficiency Testing" policy submitted with the plan of correction for the 11/6/19 recertification survey revealed "Proficiency: KOH prep and Scabies and DTM Cultures: ... In the event the testing physician's results do not match the Acceptable Results, Laboratory Director will meet with the testing physician to review results and document any discrepancies. For all Ungraded Results, Laboratory Director will review the online Participant Summary to determine the Expected Result. If the testing physician's results do not match Expected Result, Laboratory Director will meet with the testing physician to review results and document any discrepancies and discuss possible reason for discrepancies. Review of 2020, 2021, and 2022 MLE proficiency testing records revealed: 1. 1 of 5 DTM (dermatophyte test medium) samples was ungraded on the 2020 M1 test event; 2. 3 of 5 DTM samples were ungraded on the 2020 M2 test event; 3. 1 of 5 DTM samples was ungraded on the 2021 M3 test event; 4. 1 of 5 DTM samples was ungraded on the 2022 M1 test event; 5. 1 of 5 DTM samples was ungraded and the response for DTM-7 was unacceptable on the 2022 M2 test event; 6. 1 of 5 DTM samples was ungraded on the 2022 M3 test event. There was no documentation available to indicate that the ungraded and unacceptable results were evaluated to determine acceptability and appropriate corrective action.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must 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 personnel records and interview with the clinical manager 1/23/23, the laboratory director failed to ensure that prior to testing patient specimens, 1 of 9 testing personnel (TP #2) had received appropriate training and had demonstrated the ability to perform all testing operations reliably to provide and report accurate patient test results. Review of personnel records revealed TP #2 was hired in January 2022. TP #2 had competency evaluations in March 2022 and January 2023. There was no documentation of training available for review. During interview at approximately 10:05 a.m., the clinical manager confirmed there was no documentation of training for TP #2.