

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0324336	(X3) Date Survey Completed 07/11/2024
Name of Provider or Supplier Dermatology Associates Of Northern Ky Psc	Street Address, City, State 7766 Ewing Blvd Ste 100, Florence, KY	
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 Recertification Survey was conducted on 07/11/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on document review and confirmed in staff interview, the laboratory failed to verify the accuracy of the microbiology subspecialties of mycology and parasitology by semiannual proficiency testing for 1 year (2023) of 2 years reviewed (2022 and 2023). Findings included: The Laboratory Director (LD)'s "Certificate of Successful Completion," for "Clinical Laboratory and Improvement Act Testing" revealed a date of 11/21/2022. There were no further certifications related to microbiology testing in the subspecialties of mycology and parasitology found after 11/21/2022. During an interview on 07/11/2024 at 12:36 PM, the LD stated the last microbiology proficiency testing (PT) for mycology and parasitology was conducted in November of 2022. Per the LD, the proficiency testing facility closed the program that provided PT, and the laboratory did not find an alternative PT program. The LD acknowledged the laboratory failed to ensure the laboratory was enrolled in a PT microbiology program.</p>
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>

This STANDARD is not met as evidenced by:

Based on manufacturer's instructions, observation, and interview, the laboratory failed to ensure expired potassium hydroxide (KOH) reagent material was not used for patient testing in 4 of 16 examination rooms. Findings included: The manufacturer's "Instructions for Use," for "Potassium Hydroxide (KOH) Solutions," with a copyright date of 2020, revealed "Products should not be used if there are any signs of contamination, deterioration, or if the expiration date has passed." During the laboratory tour with the Laboratory Director (LD) on 07/11/2024 at 10:20 AM, the surveyor observed four KOH reagent vitals located in examination rooms had an expiration date of 12/31/2022, with a lot number of K19C21. During an interview on 07/11/2024 at 10:36 AM, the LD stated the KOH reagent vitals were located in all 16 examination rooms, which were used for patient testing. The LD acknowledged the laboratory failed to ensure expired KOH reagent was discarded and not used for laboratory testing after the printed expiration date.