Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0857923	04/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology East, Pllc	1335 Cordova Cove, Germantown, TN	

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
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 direct observation, lack of documentation, review of a patient accessioning log and final patient test report, and staff interview, the laboratory failed to enroll in proficiency testing in 2025 for the dermatophyte culture. The findings include: 1. Laboratory observation on 04/02/25 at 11:15 a.m. revealed a patient culture incubating for dermatophyte detection using Hardy Diagnostics Dermatophyte Testing Medium (DTM). 2. The laboratory failed to provide documentation of enrollment in proficiency testing for the dermatophyte culture. 3. A review of the patient accessioning log for dermatophyte culture revealed the laboratory had performed six dermatophyte cultures since 01/01/25. The last reported patient was on 03/17/25 for patient 060323. 4. The laboratory director confirmed the survey findings during an interview on 04/02/25 at 12:45 p.m.
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 direct observation, review of the laboratory's quality assessment plan for the dermatophyte testing medium (DTM), review of records, and staff interviews, the laboratory failed to follow the DTM quality assessment plan when the laboratory director did not review the required documents in 2024 and 2025. The findings include: 1. Laboratory observation on 04/02/25 at 11:15 a.m. revealed a patient culture incubated for dermatophyte detection. 2. A review of the laboratory's quality assessment portion of the individualized quality control plan revealed the laboratory director would review the temperature records, certificate of quality analysis and dermatophyte testing medium log quarterly. 3. The laboratory's temperature records revealed no documented review from April 2024 through March 2025. The dermatophyte testing medium quality certificates and sterility checks were not reviewed for lot number 626030, received on 04/03/24, lot number 638075, received on 09/12/24, or lot number 648909, received on 01/31/25. 4.The laboratory director confirmed the survey findings during an interview on 04/02/25 at 12:45 p.m.