Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0857923	09/08/2022
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of the laboratory, record request, and interview with the laboratory director, the laboratory failed to verify the accuracy of their thermometers in 2020, 2021 and 2022. The findings include: 1. Observation of the laboratory on 09 /08/2022 at 8:30 am revealed storage of dermatophyte testing medium (DTM) in a refrigerator and incubation of DTM cultures in a cabinet. The thermometers that were in use for recording temperatures were not certified. 2. Request for records documenting the accuracy of the laboratory thermometers revealed no records were available. 3. Interview with the lab director on 09/08/2022 at 11 am confirmed the laboratory did not have a process in place to verify the accuracy of thermometers used for monitoring temperatures in the refrigerator where the DTM is stored and patient DTM culture are incubated in 2020, 2021 and 2022.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure for Potassium Hydroxide (KOH), patient KOH test records, the laboratory quality assessment policy, quality assessment records and interview with the laboratory director, the laboratory's quality assessment process was not effective in preventing problems with patient test reports for two of five patients reviewed from 2020, 2021, and 2022. The findings include: 1. Review of the laboratory procedure for KOH revealed the following statement: "The analytical results are recorded in the patient chart." 2. Review of randomly selected patients (a total of five) for KOH testing revealed the following: Patient testing for KOH recorded on the KOH log for dates of 12/03/2020 for patient MW and 05/16/2022 for patient TM. The patient's charts did not include the results of the KOH for either patient. 3. Review of the laboratory's quality assessment policy revealed that assessments are performed quarterly. 4. Review of quality assessment records revealed no documentation that the reporting error was detected or corrected. 5. During an interview with the laboratory director on 09/08/2022 at 11:00 am the laboratory director stated they did not have a good process in place to ensure KOH results are entered in the final patient report destination (patient chart). The lab director confirmed the quality assessment process was not effective in preventing problems with reporting of patient KOH results.