Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0857923	05/22/2019
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: CITATION NUMBER ONE: Based on observation of the laboratory, review of the dermatophyte test medium (DTM) quality control (QC) manufacturer instructions, the laboratory QC data and interview with the laboratory director, the laboratory failed to follow the DTM QC manufacturer instructions when the patient sample for QC was not confirmed prior to use as the QC, in 2018 and 2019. The findings include: 1) Observation on May 22, 2019 at 8: 46 a.m. of the laboratory revealed DTM media in use for patient testing. 2) Review of the DTM in-house QC manufacturer instructions revealed prior to using a patient sample as QC the patient sample must be a confirmed positive by the following: initial scrapping evaluated microscopically then inoculated media produces a positive results, or a microscopic examination of the culture shows branching hyphae and the patient is cleared of fungal infection. 3) Review of the QC data revealed no confirmation of the patient QC samples as positive using either of the manufacturer two confirmation options. A new patient sample was used as positive QC with no confirmation for each new lot number, in 2018 and 2019. 4) Interview on May 22, 2019 at 11:00 a.m. with the laboratory director confirmed that the patient samples in use as QC were not confirmed positive samples as the manufacturer instructions were not followed for confirmation. CITATION NUMBER TWO: Based

	on review of the Individual Quality Control Plan (IQCP), the quarterly quality assessment (QA) documentation and interview with the laboratory director, the laboratory failed to follow the IQCP when the quarterly reviews were not performed and documented. The findings include: 1) Review of the IQCP revealed quarterly reviews are performed by the laboratory supervisor and documented. 2) Review of the QA documentation revealed no documentation of QA quarterly reviews were available for 2018 and 2019. 3) Interview on May 22, 2019 at 11:45 a.m. with the laboratory director confirmed that the QA quarterly reviews were not performed in 2018 and 2019.