Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1029474	**(X3) Date Survey Completed** 12/02/2019
Name of Provider or Supplier Park Avenue Dermatology Pa	**Street Address, City, State** 906 Park Ave, Orange Park, FL	
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	At the time of the announced, onsite recertification survey, Park Avenue Dermatology Orange Park was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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: Based on record review and interview, the laboratory failed to develop an Individualized Quality Control Plan (IQCP) for the performance of per lot or shipment quality control for the dermatophyte test medium (DTM) for two of two years reviewed (2018-2019). Findings include: Review of the laboratory's quality control procedure and quality control records showed the laboratory accepted manufacturer's media QC (quality control) and did not repeat QC with the required organisms including one that is inhibited, therefore an Individualized Quality Control Plan (IQCP) is required. During an interview on 12/2/19 at 9:00 AM, the testing person confirmed that the laboratory did not document an Individualized Quality Control Plan for the DTM for the performance of per lot or shipment quality control.