

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0602332	(X3) Date Survey Completed 03/08/2019
Name of Provider or Supplier Epstein & Epstein	Street Address, City, State 400 30th St Ste 205, Oakland, CA	
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
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> <p>This STANDARD is not met as evidenced by: Based on review of 2017 - 2019 laboratory test records for fungal cultures using DTM (Dermatophyte Test Media), and interview with an assistant, it was determined that the laboratory used fungal culture media past it's expiration date. Findings included: a. The laboratory had received and used DTM lot # D-1208-116, expiration date 11/29 /18. b. The assistant affirmed (3/08/19) the aforementioned lot number of DTM had been used for fungal cultures inoculated on 1/31/19 and 1/22/19; and thus it was determined that expired culture media was used past it's expiration date. c. The reliability and quality of Negative fungal culture results could not be assured when expired DTM was used. The assistant affirmed (3/08/19) the laboratory performed approximately 18 DTM cultures annually. Two out of 2 negative fungal cultures reviewed included one inoculated on 1/22/19 and one on 1/31/19.</p>