

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0212387	(X3) Date Survey Completed 02/28/2019
Name of Provider or Supplier Katz Dermatology	Street Address, City, State 11510 Old Georgetown Road, Rockville, MD	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and quality assurance (QA) review and interview with the testing personnel, the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The procedure, "Proficiency Testing" states that "Twice a year each testing personnel must perform a split sample test." "A proficiency form for DTMs will be filled out and placed with the DTM log. These forms will be kept for 3 years." 2. A review of QA records from 2017-2019 showed that no PT "split sample tests" were performed. There were no "proficiency forms" available at the time of the survey. 3. During an interview on 2/28/19 at 10:45 AM, the testing personnel confirmed that PT had not been performed by testing personnel from 2017-2019.</p>
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 quality control (QC) record and procedure manual review and interview with the testing personnel, the laboratory failed to ensure that the expiration dates of media used for dermatophyte testing were documented. Findings: 1. The laboratory</p>

performs dermatophyte testing using Acuderm Dermatophyte Test Media. The procedure, "Quality control/Quality Assessment" states, "When opening a new box of DTM's remove the certificate of conformity and note" "the expiration date of the lot." The "Certificate of Conformity Quality Control" sheets include the lot number of the media. 2. A review of "Certificate of Conformity Quality Control" sheets from 2017-2019 showed that sheets were present from media received 5/1/17 (lot # D-1221-0317) and from media received 2/27/19 (lot # D-1297-1018). There were no other "Certificate of Conformity Quality Control" sheets available at the time of the survey. 3. During an interview on 2/28/19 at 10:45 AM, the testing personnel confirmed that expiration dates were not documented for media used for dermatophyte testing.