

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0100947	(X3) Date Survey Completed 11/20/2019
Name of Provider or Supplier Advanced Dermcare Pc	Street Address, City, State 25 Tamarack Avenue, Danbury, CT	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's personnel competency records on 11/20/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the clinical consultant, technical supervisor, and general supervisor. b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the testing personnel on 11/20/19 at 11:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.</p>
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 record review and staff interview, the laboratory failed to verify the accuracy of microscopic potassium hydroxide (KOH) tests twice annually in the specialty of microbiology. Findings include: 1. Record review of the laboratory's personnel competency assessment records on 11/20/19 revealed that bi-annual</p>

verification for accuracy for microscopic KOH was not performed in 2017 and 2018 for 6 of 6 testing personnel. 2. Staff interview with laboratory testing personnel on 11/20/19 at 11:30 AM confirmed the above findings. 3. The laboratory performs 597 microscopic KOH tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document maintenance(s) for laboratory equipment(s) to ensure accurate and reliable test results. Findings include: 1. Record review on 11/20/19 of the equipment(s) preventive maintenance (PM) log revealed the following: a. Annual PM of the Nikon microscope (Serial # 27438) in use to read microscopic KOH was not performed and documented since 2017. b. Annual PM of the fume hood (Serial # 04D2FE327H) was not performed and/or documented since 10/4/17. 2. Staff interview with the testing personnel (TP) #1 on 11/20/19 at 11:00 am confirmed the above findings. TP#1 further stated fume hood PM was not performed to save money and the microscope was not performed because the technician was in a rush and only did PM for 2 of 3 microscopes.