

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0100947	(X3) Date Survey Completed 01/22/2018
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
D0000	The Advanced Dermcare Laboratory was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) on January 22, 2018.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document stain reactivity and characteristics on each day of testing patient samples in the sub-specialty of Histopathology. Findings include: 1. Record review of the laboratory procedure manual on 1/22/18 revealed it did not have a procedure for the evaluation of the H&E stain reactivity. 2. Record review of the H&E slides on 1/22/18 revealed documentation was not available for H&E stain quality and acceptability on each day of testing. 3. Staff interview with the testing personnel on 1/22/18 at 11:00 AM confirmed the following: a. The laboratory does not have a procedure for the evaluation of H&E stain reactivity. b. The laboratory does not document H&E stain reactivity on each day of testing to ensure stain acceptability. 4. The laboratory performs 9085 Histopathology tests annually.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education</p>

appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical supervisor (TS) failed to evaluate the competency of the testing personnel (TP) in all the 6 required components to perform high complexity laboratory testing. Findings include: 1. Record review of TP competency documents on 1/22/18 revealed TP did not have an annual competency evaluation in 2016 and 2017. 2. Staff interview with TP on 1/22/18 at 10:00 AM confirmed only a semiannual competency evaluation was performed and documented on 2/4/16 and no other competency assessment was performed thereafter. 3. The laboratory performs 9085 tests annually in the sub-specialty of Histopathology.