

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0100947	(X3) Date Survey Completed 03/10/2026
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 assess the competency for the regulatory responsibilities of the clinical consultant (CC) in the subspecialty of histopathology. Findings include: 1. Record review on 03/10/2026 of the 'Centers for Medicare & Medicaid Services - Laboratory Personnel Report - CMS 209 Form' revealed 7 of 7 CC's listed. 2. Record review on 03/10/2026 of the laboratory 'Clinical Consultant Competency Assessment Forms' for the year of 2025 revealed lack of competency assessment documentation for 7 of 7 CC's listed on the CMS-209 Form. 3. Staff interview on 03/10/2026 at 12:15 PM with the laboratory's histotechnologist #1 (HT#1) confirmed the above findings. The HT#1 further commented that he/she was unaware of the 'Clinical Consultant Competency Assessment Forms'. 4. The laboratory performs 7,505 tests annually in the subspecialty of histopathology. 5. Note this is a repeat citation.</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 follow their</p>

established policies and procedures to ensure the accuracy of the potassium hydroxide (KOH) test system is verified twice annually in the subspecialty mycology. Findings include: 1. Record review on 03/10/2026 of the laboratory's 'Biannual Testing - KOH - Provider Competency/Proficiency' log revealed lack of documentation of biannual KOH verification for the following: a. 2 of 9 testing personnel for April of 2024. b. 1 of 9 testing personnel for October of 2024. c. 3 of 9 testing personnel for April of 2025. d. 4 of 8 testing personnel for October of 2025. 2. Record review on 03/10/2026 of the laboratory's KOH policies and procedures revealed 'The laboratory director will be responsible for monitoring the bi-annual verification process to ensure that every provider is verified every six months'. 3. Staff interview on 03/10/2026 at 12:15 PM with the laboratory's histotechnologist #1 confirmed the above findings. 4. The laboratory performs 450 KOH preparations annually in the subspecialty of mycology.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview, the laboratory failed to follow manufacturer instructions for proper storage of special stain reagents in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 03/10/2026 at 9:30 AM of the of the histopathology laboratory revealed 2 of 2 Period Acid Solutions (PAS) 1% in use stored at room temperature. 2. Record review on 03/10/2026 of the PAS 1% manufacturer instructions revealed that the required storage temperature is 2 - 8 degrees Celsius. 3. Staff interview on 03/10/2026 at 9:35 AM with the laboratory's histotechnologist #1 (HT#1) confirmed the above findings. The HT#1 further commented that he/she was unaware that the PAS (1%) must be stored at 2 - 8 degrees Celsius and not at room temperature. 4. The laboratory performs 7,505 tests annually in the subspecialty of histopathology.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) 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.

This STANDARD is not met as evidenced by:
Based on surveyor observation and staff interview, the laboratory failed to ensure staining reagents and mounting medium in use did not exceed the expiration date set forth by the manufacturer in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 03/10/2026 at 9:30 AM of the histopathology laboratory revealed the following expired staining reagents and mounting medium in use: a. Phloxine 1% Aqueous - Lot # 424029 - Expiration Date: 11/22/2020 b. Phloxine 1% Aqueous - Lot # 095012 - Expiration Date: 08/15/2023 c. Phloxine 1% Aqueous - Lot # 374429 - Expiration Date: 05/24/2019 d. Periodic Acid 0.5% Aqueous - Lot # 097419 - Expiration Date: 09/23/2023 e. Acid Alcohol 1% - Lot # 083655 -

Expiration Date: 05/02/2023 f. Sulfurous Acid Rinse - Lot # 160080 - Expiration Date: 06/21/2025 g. Methylene Blue Working - Lot # 069186 - Expiration Date: 12/13/2022 h. Potassium Hydroxide 20% Aqueous - Lot # 390134 - Expiration Date: 11/15/2019 i. Carbol Fuchsin Ziehl Neelsen - Lot # 072063 - Expiration Date: 01/07/2023 j. Xylene Peanut Oil 2:1 Fite's Method - Lot # 321185 - Expiration Date: 09/11/2018 k. Surgipath Sta-On - Lot # 122121 - Expiration Date: 06/21/2022 l. Surgipath Sta-On - Lot # 041522 - Expiration Date: 10/15/2023 m. Surgipath Sta-On - Lot # 090121 - Expiration Date: 03/01/2023 n. Clarifier - Lot # 136987 - Expiration Date: 12/03/2025

2. Staff interview on 03/10/2026 at 9:40 AM with the laboratory's histotechnologist #1 confirmed the above findings. 3. The laboratory performs 7,505 tests annually in the subspecialty of histopathology.