

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2135992	<b>(X3) Date Survey Completed</b>  01/23/2026
<b>Name of Provider or Supplier</b>  Highlander Dermatology Llc	<b>Street Address, City, State</b>  16650 W Bluemound Rd, Ste B800, Brookfield, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<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 surveyor review of procedures and laboratory records and interview with the Laboratory Director, the laboratory did not establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings include: 1. Review of laboratory procedures showed no procedures for assessing employee competency for performance of potassium hydroxide (KOH) and Scabies microscopic examinations or for histopathology procedures. 2a. Review of laboratory records showed no documentation of evaluation of provider competence in performing KOH and Scabies examinations in 2024. 2b. Further review showed no semi-annual evaluation of two new providers that started testing in June 2024. 3. Interview with the Laboratory Director on January 23, 2026, at 9:45 AM confirmed the laboratory procedures did not address competence evaluations and confirmed the laboratory's documentation of competence evaluations was incomplete.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor observation of supplies and interview with the Laboratory Director, the laboratory used expired solutions and supplies. Seven of seven marking dyes, four of four potassium hydroxide (KOH), and one of one mounting media were expired. Findings include: 1. Observation in the laboratory on January 23, 2026 at 10:00 AM revealed: 1a. A single bottle of Acrymount Plus, lot 181547 with an expiration date of September 30, 2025. 1b. Seven colors of CDI's Marking Dyes: Color | Lot number | expiration date 1bi. Blue | 22111 | April 30, 2024 1bii. Red | 22077 | March 31, 2024 1biii. Black | 22075 | March 31, 2024 1biv. Yellow | 22036 | February 28, 2024 1bv. Purple | 22033 | February 28, 2024 1bvi. Orange | 22024 | January 31, 2024 1bvii. Green | 22070 | March 31, 2024 2. Observation in six procedure rooms on January 23, 2026, at 10:30 AM revealed four rooms with Delasco 10% KOH reagent available for use. All four bottles of KOH showed an expiration date of October 31, 2024. 3. Interview with the laboratory director on January 23, 2026, at 10:00 AM and 10:30 AM confirmed the laboratory used the expired supplies for patient testing.