

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0098937	<b>(X3) Date Survey Completed</b>  02/11/2025
<b>Name of Provider or Supplier</b>  Skin Cancer Center Of Fairfield County	<b>Street Address, City, State</b>  1952 Whitney Ave, 2nd Flr, Hamden, CT	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their established policies and procedures in the subspecialty of mycology. Findings Includes: 1. Record review on 02/11/2025 of the laboratory's 'KOH Proficiency and Review' binder revealed lack of documentation of 2 proficiency testing reviews by 2 of 5 testing personnel for 2024. 2. Record review on 02/11/2025 of the laboratory's 'KOH/Scabies Training, Competency &amp; Proficiency Review Policy' revealed 'Employees performing KOH testing will complete 2 proficiency reviews annually which will be read and signed by another person qualified to read KOHs the same day'. 3. Staff interview on 02/11/2025 at 11:30 AM with testing personnel #1 confirmed the above findings. 4. The laboratory performs 16 potassium hydroxide preparation/scabies tests annually in the subspecialty of mycology.</p>