

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0098937	(X3) Date Survey Completed 06/14/2021
Name of Provider or Supplier Skin Cancer Center Of Fairfield County	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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: Based on surveyor observation and staff interview, the laboratory failed to use in date reagents. Findings include: 1. Surveyor observation of the laboratory's Potassium Hydroxide (KOH) reagent on 6/14/21 at 10:45 AM revealed, the HealthLink KOH 10% (Cat# 1815) and lot # 1904311 reagent expired on 2/12/20. 2. Record review on 6/14/21 of the laboratory's KOH billing records revealed the laboratory performed 23 KOH tests in 2020 and 17 KOH tests to-date in 2021 in the sub-specialty of Mycology. 3. Staff interview with testing personnel #2 on 6/14/21 at 11:15 AM confirmed the above findings.</p>
D6070	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview the laboratory failed to document and maintain records of patient test results. Findings include: 1. Surveyor observation on 6/14/21 at 11:00 AM of the Potassium Hydroxide (KOH) test log revealed 2 of 3 testing personnel (TP) failed to document patient KOH test results in</p>

the log. 2. Record review of the KOH test log on 6/14/21 revealed records of patient KOH test log was not available in 2020 and prior to 3/15/21. 3. Record review on 6/14/21 of the laboratory's KOH billing records revealed the laboratory performed 23 KOH tests in 2020 and 17 KOH tests to-date in 2021 in the sub-specialty of Mycology. 4. Staff interview with TP#2 on 6/14/21 at 11:15 AM confirmed the above findings.