

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2109892	(X3) Date Survey Completed 04/24/2018
Name of Provider or Supplier Skin Cancer Center Of Fairfield County	Street Address, City, State 6 Business Park Dr, Ste 204, Branford, 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
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy for potassium hydroxide (KOH) preparation testing bi-annually. Findings include: 1. Record review of laboratory's proficiency testing records on 4/24/18, revealed the laboratory failed to provide evidence or documentation of bi-annual accuracy for the KOH preparation test in 2016 and 2017. 2. Staff interview with testing personnel #1 on 4/24/18 at 10:30 AM confirmed the laboratory failed to have a system in place to verify the accuracy for KOH preparation testing bi-annually in 2016 and 2017. 3. The laboratory performs 50 KOH preparations tests annually.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document maintenance for laboratory equipment to ensure accurate and reliable test results. Findings include: 1. Record review of the Olympus BH2 microscope maintenance on 4/24/18 revealed the last preventative maintenance (PM) was performed in March of</p>

2016. 2. Record review of the laboratory's PM policy on 4/24/18 revealed PM on all equipment is to be performed annually. 3. Staff interview with the testing personnel #1 on 4/24/18 at 11:00 AM confirmed that annual PM and function checks for the above microscope was overlooked and not performed in 2017. 4. The laboratory performs 50 KOH preparation tests annually.