

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D2109892	<b>(X3) Date Survey Completed</b>  03/10/2021
<b>Name of Provider or Supplier</b>  Skin Cancer Center Of Fairfield County	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6103</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to establish and follow polices/procedures for new testing personnel (TP) to evaluate and assess their skills necessary to perform laboratory testing in the subspecialty of Histopathology. Findings include: 1. Record review on 3/4/21 of laboratory's TP#2 competency records dated 3/18/19 and 9/18/20 for MOHS procedures revealed that the LD checked off TP#2 competency skills as "Demonstrates the ability to independently perform the following duties: Gross Specimens:- Maintain patient /specimen identification. Label specimen and corresponding map. Cut and orient specimens. Ink specimen." 2. Record review on 3/4/21 of TP#2 educational qualification documents revealed TP#2 did not meet the educational qualification requirements for performing high complexity testing as per CLIA regulations. 3. Record review of additional documents of MOHS maps on 3/5/21 revealed TP#2 did not perform grossing of the tissue samples. 4. Telephone staff interview with TP#1- Laboratory Supervisor on 3/5/21 at 11:00 AM confirmed: a. TP#2 never performed grossing of tissue specimens. b. The LD inadvertently checked off TP#2 competency records for grossing of specimens listed in line item 1 above. c. Only personnel performs grossing of tissue specimens are LD and TP#1. 5. Record review on 3/9/21 of a statement dated 3/9/21 by the LD revealed TP#2 never performed any grossing of tissue samples and the competency records for TP#2 were checked off by mistake. 6.</p>

Telephone staff interview with the LD on 3/10/21 at 9:55 AM confirmed he/she checked off TP#2 competency assessment records for grossing of tissue samples by mistake. 7. The laboratory performs 762 MOHS procedures annually.