

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0092534	<b>(X3) Date Survey Completed</b> 07/08/2019
<b>Name of Provider or Supplier</b> Department Of Dermatology	<b>Street Address, City, State</b> 21 South Rd 1st Fl, Ste 120, Farmington, 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>D5431</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document function checks to ensure proper functioning prior to patient testing. Findings include: 1. Record review on 7/8/19 of the laboratory's annual function checks for the 4 laboratory hoods revealed the last function check for the hoods was March 2018. 2. Record review on 7/8/19 of the 2017, 2018 and 2019 Maintenance logs for the Leica Cryostat 1860 UV located in the dermatopathology laboratory revealed: a. Only temperatures are recorded daily. b. The required cleaning and disinfection is not documented. 3. Record review on 7/8/19 of the Leica Cryostat 1860 UV Instruction Manual, Section 9: Cleaning, Disinfection, Maintenance, revealed: a. "Remove frozen section waste from the cryostat with a cold brush every day." b. "The cryostat, including all components, has to be disinfected after each daily use." 4. Staff interview with the laboratory supervisor (LS) on 7/8/19 at 11:20 AM confirmed: a. The hoods have not been checked since March of 2018. The LS stated he/she put in to have the hoods inspected and checked, but they were not done. b. The daily cleaning and disinfection of the above cryostat is not documented.</p>
<b>D6128</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually</p>

after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical supervisor failed to document annual competency of testing personnel (TP) to assess the knowledge and skills necessary to perform high complexity laboratory testing. Findings include: 1. Competency record review on 7/8/19 revealed: a. The 'UCHC Competency Checklist, Annual Dermatopathology' form used to assess annual competency was for prep tech activities only and did not contain a section for grossing. b. Annual competency assessment was not documented for 7 of 7 Grossing TP in 2017 and 2018. 2. Staff Interview with the laboratory supervisor (LS) on 7/8/19 at 10:45 AM, confirmed the above findings. The LS stated he/she was unaware that grossing was not addressed on the competency form.