

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2167375	(X3) Date Survey Completed 05/24/2021
Name of Provider or Supplier Central Connecticut Dermatology	Street Address, City, State 1 Willowbrook Rd, Ste 2, Cromwell, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide evidence of monitoring and documenting humidity requirements. Findings include: 1. Record review on 5/24/2021 of the laboratory room temperature logs for the years 2020 and 2021 revealed the following: a. Acceptable humidity readings were less than 60 percent(%). b. Statement indicating "The humidity will be documented at the beginning of each work day. Any corrective action will be documented for out of range and addressed immediately." c. No documentation of humidity levels were recorded for either year. 2. Record review on 5/24/2021 of the 'Leica Biosystems CM1520 Cryostat Instructions for Use V1.5 RevG 10/2016' manual revealed the acceptable humidity condition is less than 80%, non-condensing. 3. Staff interview on 5/24/2021 at 10:53 AM with Laboratory Director (LD) confirmed the above findings. 4. The laboratory performs 2,816 MOHS micrographic surgery procedures annually in the subspecialty of histopathology.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document corrective action when temperatures exceeded established acceptable ranges in the subspecialty of histopathology. Findings include: 1. Record review on 5/24/2021 of the laboratory room temperature logs for the years 2020 and 2021 revealed the following: a. Acceptable room temperature range was 65 to 72 Fahrenheit (F). b. Corrective action was not documented for 121 of 230 working days from January 2020 through December 2020 when the room temperature was outside of the range in 1a above. c. Corrective action was not documented for 30 of 99 working days from January 2021 through May 24, 2021 when the room temperature was outside of the range in 1a above. 2. Record review on 5/24/2021 of the laboratory cryostat temperature logs for the years 2020 and 2021 revealed the following: a. The laboratory utilizes two cryostats designated 'CM1520 Left' and 'CM1520 Right.' b. The acceptable range for both cryostats was -20 to -30 Celsius. c. Corrective action for 'CM1520 Left' was not documented for 20 of 231 working days from January 2020 through December 2020 when the cryostat temperature was outside of the range in 2b above. d. Corrective action for 'CM1520 Left' was not documented for 36 of 99 working days from January 2021 through May 24, 2021 when the cryostat temperature was outside of the range in 2b above. e. Corrective action for 'CM1520 Right' was not documented for 20 of 228 working days from January 2020 through December 2020 when the cryostat temperature was outside of the range in 2b above. f. Corrective action for 'CM1520 Right' was not documented for 22 of 97 working days from January 2021 through May 24, 2021 when the cryostat temperature was outside of the range in 2b above. 3. Staff interview on 5/24/2021 at 10:53 AM with Laboratory Director (LD) confirmed: a. The above ranges were acceptable and actively reviewed monthly. b. Documentation of corrective action was not recorded. 4. The laboratory performs 2,816 MOHS micrographic surgery procedures annually in the subspecialty of histopathology.