Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0902738	02/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatopathology Lab Of New England Pc	140 Green Road, Meriden, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform manufacturer recommended routine maintenance for the cover-slipper equipment at the required frequency. Findings include: 1. Record review of the laboratory's cover-slipper (Leica CV5030 SN# 3992) maintenance log on 2/5/19 revealed the lack of documentation for daily maintenance as listed below: a. March 2018: 13 working days. b. April 2018: 12 working days. c. May 2018: 15 working days. d. June 2018: 13 working days. e. July 2018: Document not available. f. August 2018: 14 working days. g. September 2018: 13 working days. h. October 2018: 14 working days. i. November 2018: 11 working days. j. December 2018: 11 working days. k. January 2018: 13 working days. 2. The above document further revealed the lack of: a. Semiannual maintenance at the required frequency in 2018. b. Monthly supervisor review. 3. Staff interview with testing personnel#1 (TP#1) on 2/5/19 at 11:30 AM confirmed the above findings. TP#1 stated there was change in staffing and he/she was unaware daily maintenance were not being performed or documented as required. 4. The laboratory performs 21,341 tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken 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 observation, record review and staff interview, the laboratory failed to take corrective action when the laboratory's oven and refrigerator temperatures were out of range. Findings include: 1. Surveyor observation on 2/5/19 at 9:00 AM of the laboratory's oven thermometer (Enviro-Safe R09643) revealed the green dye was broken and could not obtain accurate temperature reading. 2. Record review of the laboratory's oven (for warming slides-LC Model # 3511) temperature log on 2/5/19 revealed: a. Acceptable temperature range was 80-90C in January and February 2017 and the temperatures were out of range 6-20 days each month. b. Acceptable temperature range was 60-70C in March and April 2017 and the temperatures were within range. c. Acceptable temperature range was 80-90C in May and June 2017 and the temperatures were out of range 22 days each month. d. Acceptable temperature range was 60-70C and the temperatures were within range in July 2017. e. Acceptable temperature range was 70-80C in August and September 2017 and the temperatures were out of range 4 days in September 2017. f. Acceptable temperature range was 80-90C from October through December 2017 and the temperatures were out of range 20-22 days each month. g. Acceptable temperature range was 80-90C and the temperatures were out of range on 22 days in January 2018. h. Acceptable temperature range was 65-75C and the temperatures were within range in February 2018. i. Acceptable temperature range was 80-90C from March through December 2018 and the temperatures were out of range 18-23 days each month. j. Acceptable temperature range was 80-90C and the temperatures were out of range 21 days in January 2019. k. Documentation for corrective action for the above out of range temperatures were not available. 3. Records review of the laboratory's refrigerator (for storing test reagents) temperature log on 2/5/19 revealed: a. Acceptable refrigerator temperature is listed as 4-6C. b. Refrigerator temperatures were out of range 12-19 days from April 2018 through January 2019 each month. c. Documentation for corrective action for the above out of range temperatures were not available. 4. Staff interview with testing personnel #1(TP#1) on 2/5/19 at 11:30 AM confirmed the above findings. TP#1 stated oven temperature range was changed to 60-70C in 2017 but documentation for validation was not available. TP#1 further stated he/she was not aware the oven thermometer was broken. 5. The laboratory performs 21,341 tests annually in the specialty of Pathology
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure competency assessment for all testing personnel (TP) includes testing previously analyzed

	specimens, blind samples or external proficiency testing (PT) samples in the sub-specialty of histopathology. Findings include: 1. Record review on 2/5/19 of the laboratory's 2017 and 2018 peer review competency evaluation records revealed the laboratory failed to provide evidence of documentation for 1 of 3 TP in 2017 to ensure the TP was assessed using previously analyzed specimens or blind samples to accurately assess their skills in professional interpretation of test results. 2. Staff interview with the laboratory manager (LM) on 2/5/19 at 10:00 AM confirmed the above finding. LM stated the above TP performed few test interpretations in 2017. 3. The laboratory performs 21,341 tests annually in the specialty of Pathology.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview the technical supervisor failed to asses and document testing personnel (TP) competency to perform high complexity testing in the sub-specialty of histopathology twice in the first year of performing patient testing. Findings include: 1. Record review of TP competency evaluation records on 2 /5/19 revealed 1 of 2 TP hired since last CLIA recertification survey was not assessed for their competency to perform grossing of patient samples twice during the first year of employment. 2. Staff interview with the laboratory supervisor on 2/5/19 at 10:30 AM confirmed: a. TP was hired in May 2017 and testing patient samples since then. b. TP was not evaluated for his/her competency twice during the first year employment. c. TP was rehired in 2017 after a break in the employment.