

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0685481	<b>(X3) Date Survey Completed</b> 03/17/2025
<b>Name of Provider or Supplier</b> Lawrence J Fortier, Md	<b>Street Address, City, State</b> 465 Silas Deane Highway, Wethersfield, 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>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview the laboratory failed to document eyewash function check at the required frequency in the subspecialty of Histopathology. Findings include: 1. Surveyor observation on 3/17/2025 at 9:45 AM of the laboratory processing room revealed a plumbed eyewash located in the sink. 2. Record review on 3/17/2025 of the "Fire extinguisher &amp; Eye Wash Log-check weekly" logs in the "SOP Binder" revealed lack of documentation of weekly eye wash check since January 2023. 3. Staff interview on 3/17/2025 at 10:14 AM with the Histotechnician (HT) confirmed that he/she did not perform and document weekly eyewash checks. 4. The laboratory performs 528 Mohs Micrographic Surgery cases annually in the subspecialty of Histopathology.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow their</p>

established "Quality Assurance" policy to review all the documents monthly in the subspecialty of Histopathology. Findings include: 1. Record review on 3/17/2025 of the laboratory's "Quality Assurance Policy" revealed, "Quality control assessment: Laboratory Director (LD) continually monitor quality control results by reviewing all aspects of the laboratory note book monthly and implement corrective action as needed". 2. Record review on 3/17/2025 of the "Cryostat Temperature Logs- Range -20 C to -30 C" revealed lack of documentation of the LD's monthly review for all the 3 of 3 years as listed below. 3. Record review on 3/17/2025 of the "Cryostat Temperature Logs- Range -20 C to -30 C" revealed lack of documentation for corrective action for not documenting the cryostat temperatures for all of the days listed below: a. 211/211 days of patient testing for the year 2023. b. 208/208 days of patient testing for the year 2024. c. 46/46 days of patient testing for the current year 2025. 4. Staff interview on 3/17/2025 at 10:14 AM with the Histotechnician confirmed the findings listed 2 above. 5. The laboratory performs 528 Mohs Micrographic Surgery in the subspecialty of Histopathology.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
A. Based on surveyor observation, record review and staff interview the laboratory failed to document room temperature and humidity on the day of patient testing in the subspecialty of Histopathology. Findings include: 1. Surveyor observation on 3/17/2025 at 9:42 AM of the laboratory processing room revealed a thermometer /hygrometer located on the shelf. 2. Record review on 3/17/2025 of the laboratory's "Equipment Maintenance procedure" in the "SOP Binder" stated, "Temperature of the lab is monitored and recorded daily (20 degree C to 30 degree C) in the maintenance log. Humidity of the lab is monitored and recorded daily (60 % max) in the maintenance log". 3. Record review on 3/17/2025 of the Binder with daily patient log, revealed lack of documentation of the daily room temperature and humidity for the following: a. 211/211 days of patient testing for the year 2023. b. 208/208 days of patient testing for the year 2024. c. 46/46 days of patient testing for the current year 2025. 4. Staff interview with the Histotechnician on 3/17/2025 at 9:43 AM confirmed that the laboratory did not document daily room temperature and humidity. He/she further stated the room temperature and humidity was checked but not documented as the laboratory had a controlled environment. 5. The laboratory performs 528 Mohs Micrographic Surgery cases annually in the subspecialty of Histopathology. B. Based on surveyor observation, record review and staff interview the laboratory failed to document cryostat temperature on the day of patient testing in the subspecialty of Histopathology. Findings include: 1. Surveyor observation on 3/17/2025 at 9:42 AM of the laboratory processing room revealed a "Leica-CM-1510"-Cryostat in use by the Histotechnician. 2. Record review on 3/17/2025 of the laboratory's "Equipment Maintenance procedure" in the "SOP Binder" stated, "Temperature of Cryostat is

monitored and recorded daily (-20 degree C to -30 degree C) in the maintenance log".

3. Record review on 3/17/2025 of the laboratory's "Cryostat Temperature Logs-Range -20 C to -24 C", revealed initials of HT and lack of cryostat temperature documentation on the day of patient testing for the following: a. 211/211 days of patient testing for the year 2023. b. 208/208 days of patient testing for the year 2024. c. 46/46 days of patient testing for the current year 2025.
4. Staff interview on 3/17/2025 at 10:14 AM with the HT confirmed the laboratory does not document the cryostat temperature on the day of patient testing, instead puts initials on the log. He/she further commented of not being aware of actual temperatures to be documented.
5. The laboratory performs 528 Mohs Micrographic Surgery cases annually in the subspecialty Histopathology.