

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0666646	<b>(X3) Date Survey Completed</b>  12/03/2024
<b>Name of Provider or Supplier</b>  Lawrence & Memorial Hospital Laboratory	<b>Street Address, City, State</b>  365 Montauk Avenue, New London, 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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor observation, record review and staff interview, the laboratory failed to follow manufacturer's instructions for storage of the QwikCheck Quality Control Beads (QCB) for semen analysis in the specialty of Hematology. Findings include: 1. Surveyor observation on 12/03/2024 at 11:00 AM of the laboratory's Helmer refrigerator used for storage of controls and reagents revealed of the following: a. 2 of 4 QCB kits, lot number 110724 labeled "In Use". b. 2 of 4 QCB kits, lot number 010924 labeled "New lot-Do not Use". c. The storage requirements on QCB kits indicated "15 to 30 degrees Celsius". 2. Record review on 12/03/2024 of the "QwikCheck Beads- Quality Control Beads for automated and manual sperm counting devices" package insert provided by the manufacturer revealed, "Storage Conditions: Store the beads @ 15-30 degree C (60-86 degree F). Open Vial beads can be stored @ 15-30 degree C (60-86 degree F) for 90 days." 3. Record review on 12/03/2024 of the laboratory's approved "LM Semen Analysis" procedure manual, the "Quality Control" section revealed the following: a. "The QC bead kit is to be stored at room temperature (2-8 degree C)." b. "Store at room temperature (20-25 degree C or 65-77 degree F)." NOTE: The storage requirements of the QCB listed in 3a and 3b above are contradicting. 4. Staff interview with the General Supervisor (GS) on 12/03/2024 at 12:05 AM confirmed the findings in 3 above. The GS further confirmed the storage temperature requirements in the package insert were not being followed by the laboratory. The GS further stated, "The test was moved from the microbiology section to hematology section, and the microbiology section supervisor had mentioned to</p>

store the QCB at 2 to 8 degree C for the QC to pass." 5. The laboratory performs 188 semen analysis tests annually.