

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0933626	(X3) Date Survey Completed 10/06/2023
Name of Provider or Supplier Cattail River Hematology & Oncology	Street Address, City, State 3418 Olandwood Court #111, Olney, MD	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's certificate of accuracy, review of the laboratory's procedure, and interview with the testing person (TP), the laboratory failed to verify the accuracy of the Streck Temp-Chex thermometers. Findings: 1. The laboratory monitored refrigerator and freezer temperatures using Streck Temp-Check thermometers. 2. The Streck Temp-Chex thermometer Instructional Information and Certificate of Accuracy stated "Due to use in diverse applications and handling, there is no precise way to predict how long calibration will be maintained. As with any thermometer, drift is a possibility and accuracy can be affected by shock, aging, temperature and contamination through daily use. Periodic recalibration or verification should be scheduled by each laboratory in accordance with its accrediting agency and/or established procedure. At a minimum, annual recalibration or verification from the date the thermometer is put 'in use' is good lab practice." 3. The laboratory did not have a procedure defining the frequency with which to verify the accuracy of the Streck Temp-Chex thermometers. 4. During the survey on 10/06/2023 at 1:15 PM, the TP confirmed that the Streck Temp-Chex thermometers have not been recalibrated/verified since put into use and the laboratory did not have a procedure for verifying the accuracy of the thermometers.</p>