

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2298418	(X3) Date Survey Completed 11/14/2024
Name of Provider or Supplier Carbon Hill Family Care Llc	Street Address, City, State 31040 1st Ave Ne Suite 6, Carbon Hill, AL	
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 a review of the Room Temperature (RT) and Humidity logs, the Medonic M-Series Hematology analyzer user manual, and an interview with the laboratory's co-owner (LA), the laboratory failed to record the RT and Humidity each day of patient testing. This was noted from the date patient testing started on 3-6-2024 to the date of the initial survey on 11-14-2024. The findings include: 1) A review of the RT and Humidity logs revealed the staff did not monitor and document the RT and Humidity of the laboratory from February 2024 through November 2024 when patient testing was performed. 2. A further review of the Medonic M-Series Hematology analyzer user manual revealed manufacturer's specifications of RT at 64 - 90 degrees Farenheit and Humidity of less than or equal to 80% when patient testing were performed. 3) During the exit conference with LA on 11-14-2024 at 4:20 PM, she confirmed the above findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the</p>

manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the Hematology calibration records, the Medonic M-series (MMS) operator's manual, and an interview with laboratory's co-owner (LA), the laboratory failed to perform calibrations on the MMS Hematology analyzer as per manufacturer's specifications. The surveyor noted one missing calibration from the date of the MMS install on 2-22-2024 to the current survey of 11-14-2024. The findings include: 1. A review of the Hematology calibration records revealed the MMS analyzer was calibrated 2-22-2024 when it was installed. There was no evidence of documented calibration found when it was due to be performed between August and September 2024. 2. A further review of the MMS analyzer manual revealed calibration requirement of at least every six months after instrument set-up. 3. During the exit conference with LA on 11-14-2024 at 4:20 PM, LA mentioned the missed calibration was due to the testing personnel assigned to monitor the laboratory had taken a leave of absence and never came back due to personal reasons.