

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0990794	<b>(X3) Date Survey Completed</b> 11/12/2019
<b>Name of Provider or Supplier</b> White Oak Urgent Care Randleman	<b>Street Address, City, State</b> 608 West Academy Street, Randleman, NC	
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>D5413</b>	<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 review of manufacturer's instructions and review of the laboratory's 2017, 2018, and 2019 temperature and humidity logs 11/12/19, the laboratory failed to establish an acceptable range for room humidity that was consistent with manufacturer's instructions for operation of the Medonic M-series hematology analyzer. Review of the Medonic M-series User's Manual revealed the manufacturer specifies that the analyzer be operated in an environment with a humidity less than or equal to 80%, noncondensing. Review of the laboratory's 2017, 2018, and 2019 temperature and humidity logs revealed an acceptable range for humidity of 15-85%.</p>
<b>D5437</b>	<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 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,</p>

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 review of manufacturer's instructions and review of 2017, 2018, and 2019 hematology records 11/12/19, the laboratory failed to perform and document calibration of the Medonic M-series hematology analyzer at least once every six months as required. The Medonic M-series User's Manual states "Section 7: Calibration ... Introduction ... It is recommended to calibrate the instrument every 6 months. ... " Review of 2017, 2018, and 2019 hematology records revealed the Medonic M-series analyzer was not calibrated at least once every six months as specified by the manufacturer. Calibration was performed on 11/30/17, 4/3/18, eight months later on 12/18/18, 3/21/19, and eight months later on 11/4/19.