

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2221531	<b>(X3) Date Survey Completed</b>  12/06/2024
<b>Name of Provider or Supplier</b>  Accu Refernce Medical Lab	<b>Street Address, City, State</b>  706 E 5th St, Tabor City, 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 operator's manual, review of 2022, 2023, and 2024 laboratory logs, and interview with the Laboratory Director (LD) 12/06/2024, the laboratory failed to ensure that the established room temperature ranges for the hematology analyzer were within operator's manual requirements. Findings: Review of "Cell-DYN Emerald Operator's Manual" hematology analyzer, Section 2, Site Requirements page 2-3, revealed "...maintain the temperature between 64 - 90 F (18 - 32 C)". Review of "AccuReference Lab" laboratory logs, revealed room temperature range "... acceptable range 15 - 30 C". The laboratory's established room temperature range 15 - 30 C does not meet the operator's manual requirements 18 - 32 C. During interview at approximately 1:20 p.m., LD confirmed incorrect room temperature in use on AccuReference Lab logs.</p>