

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2041950	<b>(X3) Date Survey Completed</b>  06/14/2022
<b>Name of Provider or Supplier</b>  Pell City Internal And Family Medicine	<b>Street Address, City, State</b>  41 Eminence Way Suite A, Pell City, AL	
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 a review of the temperature records, a review of the BioRad Liquid Assayed MultiQual Quality Control (QC) package insert, and an interview with the Technical Consultant, the surveyor determined the laboratory's criteria for Freezer temperatures failed to be consistent with the manufacturer's storage requirements. The laboratory further failed to ensure QC was stored as per manufacturer's requirements for five out of five months from September 2021 to May 2022 reviewed by the surveyor. The findings include: 1. A review of temperature records revealed the acceptable range for the Freezer was -12 to -20 degrees Celsius. The temperature records also revealed the following: a) September 2021 - 13 days were warmer than -20 degrees Celsius. b) November 2021 - 23 days were warmer than -20 degrees Celsius. c) January 2022 - 19 days were warmer than -20 degrees Celsius. d) March 2022 - 13 days were warmer than -20 degrees Celsius. e) May 2022 - 8 days were warmer than -20 degrees Celsius. 2. A review of the BioRad Liquid Assayed MultiQual QC package insert revealed storage requirements of -20 to -70 degrees Celsius. 3. During an interview on 06/14 /2022 at 1:00 PM, the Technical Consultant confirmed the above findings.</p>