

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304601	<b>(X3) Date Survey Completed</b>  07/13/2022
<b>Name of Provider or Supplier</b>  Clay County Hospital Laboratory	<b>Street Address, City, State</b>  83825 Highway 9, 1st Floor South Hall, Ashland, 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 Cobas b221 analyzer records (used for performing Arterial Blood Gases [ABGs] in the Respiratory Therapy Department and an interview with Testing Personnel #10 (the Respiratory Therapy Supervisor), the laboratory failed to ensure the kit for the June 2021 calibration verification was utilized before expiration. This affected one of four ABG calibration verifications performed in 2021-2022. The findings include: 1. A review of the Cobas b221 ABG analyzer records revealed the June 2021 calibration verification was performed on July 31, 2021. The laboratory utilized Lot # 21491930 with an expiration date of June 2021. 2. During an interview on July 13, 2022, at 12:59 PM, testing personnel #10 confirmed the above noted findings. SURVEYOR ID# 32558 Licensure and Certification Surveyor</p>