

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305732	<b>(X3) Date Survey Completed</b>  09/13/2022
<b>Name of Provider or Supplier</b>  Southern Cancer Center	<b>Street Address, City, State</b>  6701 Airport Blvd, Mobile, 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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on an observation in the laboratory, a review of the Audit MicroControls Linearity FD Bilirubin Supplement package insert, and an interview with the Technical Consultant, the laboratory failed to adhere to conditions of storage for reagents. The findings include: 1. During the laboratory tour, the surveyor observed an unopened box of Audit MicroControls Linearity FD Bilirubin Supplement stored in a freezer set at -20 degrees Celcius. 2. A review of the Audit MicroControls Linearity FD Bilirubin Supplement package insert revealed the storage requirements of 2 to 8 degrees Celcius. 3. During an interview on 09/13/2022 at 9:45 AM, the Technical Consultant confirmed the above findings.</p>