

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2199878	<b>(X3) Date Survey Completed</b>  03/01/2022
<b>Name of Provider or Supplier</b>  Agile Biodetection	<b>Street Address, City, State</b>  105 Vulcan Road, Suite 400, Homewood, 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 Testing Processes Procedure, CFX96 Touch Deep Well RealTime PCR detection Systems Safety Manual, and an interview with the Laboratory Director, the laboratory failed to monitor and document Room Temperature and Humidity. This was noted from November 2021 (when patient testing started) to March 2022 (date of survey). The findings include: 1. A review of the Testing Processes Procedure revealed "...Each day the laboratory is open, environmental conditions, such as refrigerator, room temperature and humidity, are monitored and recorded..." 2. A review of the CFX96 Touch Deep Well RealTime PCR detection Systems Safety Manual revealed "...Temperature - Ambient temperature of 15 - 31 degrees Celsius. Relative humidity maximum of 80% noncondensing..." 3. During an interview on 03/01/2022 at 11:30 AM, the Laboratory Director confirmed Room Temperature and Humidity had not been monitored.</p>