Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D2246258	**(X3) Date Survey Completed** 03/16/2022
Name of Provider or Supplier Well Health Labs Of Alabama	**Street Address, City, State** 715 Skyland Blvd East Suit 2, Tuscaloosa, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on a review of temperature logs, Temperature Monitoring Procedure, CFX Opus 384 Operator's Manual, and an interview with the General Supervisor, the laboratory failed to document room temperature and humidity for the laboratory. This was noted from first date of patient testing (January 31, 2022) to date of survey (March 16, 2022). The findings include: 1. A review of temperature logs revealed no room temperature and humidity being documented for the laboratory. 2. A review of the Temperature Monitoring Procedure revealed "...Temperatures to be monitored include Room, Refrigerator, Freezer, and Incubator (when in use). Humidity of the instrument room should be monitored..." 3. A review of the CFX Opus 384 Operator's Manual revealed the environment requirements for operating conditions 15 to 31 degrees Celsius for room temperature and 0 - 80% relative humidity. 4. During an interview on 03/16/2022 at 11:20 AM, the General Supervisor confirmed the room temperature and humidity were being monitored, but not documented.