Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0927346	12/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Medical West Hospital Authority	995 9th Avenue Sw, Bessemer, 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 the refrigerator and room temperature records, humidity records, Quality Assurance (QA) procedure, and an interview with the Technical Consultant, the Laboratory failed to document refrigerator and room temperatures and humidity. This was noted for 65 days in 2022 and 17 days in 2023. The findings include: 1. A review of the refrigerator temperature records revealed the laboratory failed to document temperatures for the refrigerator for 34 days in 2022. 2. A review of room temperature and humidity records revealed the following days not documented: a) 31 days in 2022 b) 17 days in 2023 2. A further review of the Environmental Monitoring of Laboratory procedure revealed, "Check thermometers and hygrometer daily... Refrigerator... Room Temperature and Room Humidity." 3. During an interview on 12 /19/2023 at 1:10 PM, both Technical Consultants confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the room temperature and humidity records, and an interview with the Technical Consultant, the Laboratory failed to document corrective actions when room temperatures and humidity were outside the manufacturers' range. This was noted for 38 days reviewed in 2022 through 2023. The findings include: 1. A review of room temperatures and humidity records revealed room temperatures and humidity were not within range with no documentation of corrective action for the following: a) Room temperature for 20 days in 2022. b) Room temperature for 9 days in 2023. c) Humidity for 9 days in 2023. 2. During an interview on 12/19/2023 at 1:10 PM, the Technical Consultant confirmed the above findings.