Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306184	08/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Whitfield Regional Hospital	105 Highway 80 East, Demopolis, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Sickle-Chek Quality Control (QC) records, the Sickle-Chek patient log, the Sickle-Chek Information For Use (IFU) and an interview with Testing Personnel #1, the laboratory utilized expired Sickle-Chek QC prior to patient testing. The surveyor noted one patient was performed using expired Sickle-Chek QC in 2024. The findings include: 1. A review of the Sickle-Chek QC records revealed the Sickle-Chek QC was opened 3/20/24 and expired 6/28/24, one patient was performed on 8/5/24. 2. A further review of the Sickle-Chek IFU revealed, "Sickle-Chek...Open-vial stability is 100 days after opening." 3. During the exit interview on 8/20/2024, at 2:35 PM, Testing Personnel #1 confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Hematology maintenance records and an interview with the Laboratory Manager, the Laboratory failed to document monthly maintenance on the Beckman Coulter DxH 690 T Hematology analyzer as per the manufacturer's

	requirements. This was noted for three of eight months reviewed in 2024. The findings include: 1. A review of the Beckman Coulter DxH 690 T Hematology analyzer records revealed no documentation of monthly maintenance in April, May, and June of 2024. 2. During an interview on 8/20/24, at 1:30 PM, the Laboratory Manager 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 refrigerator temperature records, the ABL 90 Sensor Cassette specifications, and an interview with the Laboratory Manager, the Laboratory failed to implement and document corrective actions when the refrigerator temperature was outside the manufacturers' storage parameters for items therein. The surveyor noted refrigerator temperatures were below acceptable ranges for 18 of 18 months, reviewed from 2023 through 2024, with no documentation of corrective action. The findings include: 1. A review of the refrigerator temperature records revealed refrigerator temperatures were outside the manufacturers' storage parameters of 2-8 degrees Celsius with no evidence of documentation of corrective action for the following months: a) 2023: March through December. b) 2024: January through August. 2. A further review of the specifications for the ABL 90 Blood Gas Analyzer Sensor Cassette specifications revealed, "sensor cassette specifications require storage of 2-8 degrees Celsius." 3. During an interview on 8/20/24, at 1:30 PM, the Laboratory Manager confirmed the above findings.