Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306184	06/30/2021
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Operator's Manual for the ABL 90 Flex Plus Arterial Blood Gas (ABG) analyzer, a review of calibration verification (C/V) records for two ABL 80 analyzers and the ABL 90 Flex Plus analyzers, and an interview with the Respiratory Therapy Supervisor, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations. The surveyor noted four C/V's were late or not performed from January 2019 thru June 2021. The findings

	include: 1. A review of the ABL 80 and ABL 90 Flex Plus ABG analyzer records revealed the following: A--ABG Analyzer ABL 80 "A" a) C/V on 8/06/2018 (there was no indication if this was "A" or "B") b) C/V on 7/09/2019 (eleven months after the previous C/V) c) C/V on 12/3/2019 d) No documentation of a C/V on ABL 80 "A" the first half of 2020 B--ABG Analyzer ABL 80 "B" a) C/V on 8/06/2018 (there was no indication if this was "A" or "B") b) C/V on 7/09/2019 (eleven months after the previous C/V) c) C/V on 12/3/2019 d) C/V on 10/20/2020 (ten and a half months after the previous C/V) C--ABG Analyzer ABL 90 Flex Plus "021" (replacement for the ABL 80 analyzers) a) C/V on 11/12/2020 (during the installation and validation) b) No documentation of a C/V on ABL 90 "021" the first half of 2021 2. A review of the Operator's Manual for the ABL 90 Flex Plus ABG analyzer under "Frequency of Calibration Verification" revealed, "Follow your local, state or federal regulations." Note: Analytes calibrated with less than three calibrators must have a calibration verification performed every six months as per federal CLIA regulations. 3. During an interview at 12:15 PM on 6/30/2021, the Respiratory Therapy Supervisor confirmed the laboratory had missed performing some C/V's and some had been late. The surveyor then asked how often should a C/V be performed; the Supervisor stated, "Every six months". .
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing records and an interview with the Technical Supervisor, the surveyor determined the Technical Supervisor failed to ensure Immunohematology / Immunology results for one of three 2019 surveys, and Microbiology results for one of three 2020 surveys were submitted within the timeframes specified by the proficiency testing program. The findings include: 1. A review of the results from the 2019-Event #2 Immunohematology / Immunology survey (for Blood Bank, Syphilis Serology, C-Reactive Protein and Rheumatoid Factor testing) revealed 0% (percent) scores for all parameters due to failure to participate. 2. A review of the results from the 2020-Event #2 Microbiology survey revealed 0% scores for all tests due to failure to participate. 3. During an interview on 6/29/2021 at 4:10 PM, the Technical Supervisor confirmed the laboratory testing personnel had entered the results for the above surveys on the API website, however the Supervisor had missed completing the final step for submission to API before the cutoff dates, due to other responsibilities. SURVEYOR ID# 32558 Licensure and Certification Surveyor