Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0651947	10/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson Davis Community Hospital	1102 Rose Street, Prentiss, MS	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Stago STA Satellite coagulation system, documentation of establishment of the geometric mean of the normal patient reference range for STA-Neoplastine C1 Plus prothrombin time (PT) reagent Lot #258994, observation of the Reference Time in the STA Satellite coagulation system on 10/3/22 at 10:00 a.m., and patient test logs, the laboratory failed to follow manufacturer's instructions for setting up the STA Satellite coagulation system to calculate the INR (international normalized ratio) for patient PT testing when PT reagent Lot #258994 was put in use for patient testing on 2/23/22. A total of 186 patient prothrombin time results were reported from 2/23/22 until 10/3/22. Findings include: Manufacturer's instructions for the Stago STA Satellite coagulation system state to enter the normal range geometric mean as the Reference Time with each new lot of PT reagent for correct calculation of the INR. Review of documentation of the establishment of the geometric mean of the normal patient reference range for STA-Neoplastine C1 Plus PT reagent Lot #258994, put in use on 2/23/22, revealed the geometric mean was calculated as 13.7. The Reference Time observed in the STA Satellite coagulation system on 10/3/22 at 10:00 a.m. was 13.1. Review of patient test logs revealed 186 patient PT results were reported form 2/23/22 until 10/3/22.
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 review of calibration verification records since the last survey on 10/16/20 and interview on 10/4/22 at 4:00 p.m. with Technical Consultant #1 listed on the CMS 209 personnel form, the laboratory failed to perform calibration verification on the Radiometer ABL80 Co-Ox Flex analyzer for blood gas testing - pH, pO2, and pCO2 - at least every six months since the Radiometer ABL80 Co-Ox Flex analyzer was put in use on 8/14/20. The laboratory's annual volume for blood gases is 93. Findings include: Review of calibration verification records since the last survey on 10/16/20 revealed calibration verification was not performed on blood gas testing on the Radiometer ABL80 Co-Ox Flex analyzer since it was performed at installation in August 2020. Technical Consultant #1 confirmed in an interview on 10/4/22 at 4:00 p. m. that calibration verification was not performed since August 2020, and the laboratory's annual volume for blood gases is 93.