Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0666871	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Greenville Family Medical Center, Inc	1467 Hwy 1 S, Greenville, 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Cell Dyn Emerald hematology calibration records from last survey 10/17/19 through 2/16/22 and interview with the TP #1 and the technical consultant (TC) at 3:30 p.m. on the day of survey, 2/16/22, the laboratory failed to perform calibration on CBC (complete blood count) performed on the Cell Dyn Emerald hematology every 6 months as required by the manufacturer. Findings include: 1. Review of the Cell Dyn Emerald calibration records revealed calibration was performed on 10/28/19, 10/3/20, 12/11/20, and 11/14/21. These calibration date time frames exceed the 6 month mandatory calibration requirement 2. Interview with the TC and TP #1 at 3:30 p.m. on 2/16/22 confirmed CBC calibrations were not performed every 6 months as evidenced by the calibration records available.
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 the Biosite Triage Meter chemistry laboratory records, lack of documentation and interviews with testing personnel (TP) #1 and the technical consultant (TC) at 2:30 p.m. on 2/16/22, the laboratory failed to perform calibration verification on the Biosite Triage Meter every 6 months for troponin, myoglobin and the CKMB. Findings include: 1. Review of the Biosite Triage records from 10/17/19 through 2/16/22 revealed only one documented calibration verification performed on the Triage Meter for troponin, myoglobin or CKMB on 10/11/21. 2. Calibration verification is required by the manufacturer, initially and every 6 months on the Biosite Triage Meter for all moderate complexity tests performed. 2. TP #1 and the TC confirmed in an interview at 2:30 p.m. on 2/16/22 that there was only one calibration verification documented for myoglobin, troponin and CKMB over the 28 month period surveyed.