Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316773	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bolivar Phys Pract Dba Cleveland Medical Clinic	810 East Sunflower Road Ste 100-A, Cleveland, 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
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: A. Based on review of Biosite Triage Meter records from 12/3/18 through 4/14/21, and confirmation with testing personnel (TP) #1, the laboratory failed to perform calibration verification on the Biosite Triage Meter chemistry analyzer every 6 months for D-dimer. Findings include: 1. Review of the laboratory Biosite Triage Meter D-dimer records from 12/3/18 through 4/21/21 revealed calibration verification had not been performed every 6 months as required by the manufacturer. 2. Review of

	the Biosite Triage Meter D-dimer records from 12/3/18 through 4/14/21 revealed calibration verification had been performed on 12/26/18, 6/5/19, 12/11/19 and 9/22 /20. The time period from 12/11/19 to 9/22/20 and 9/22/21 until 4/21/21 exceed the manufacturer's calibration verification requirements. 3. Interview with TP #1 at 2:00 pm on 4/21/21 confirmed that calibration verification had not been performed on the D-dimer every 6 months. B. Based on review of the Abbott i-Stat records from 1/14 /20 through 3/31/21, and confirmation with TP #1, the laboratory failed to perform calibration verification on the Abbott i-Stat chemistry analyzer every 6 months for the Chem 8 profile (Sodium, Potassium, CO2, Blood Urea Nitrogen (BUN), Chloride, Glucose, Creatinine, Calcium and Hematocrit). 1. Review of the Abbott i Stat records from 1/14/20 through 3/31/21 revealed calibration verification had not been performed on the Chem 8 panel since categorized as nonwaived testing on 1/14/20. 2. Interview with TP #1 at 2:00 pm on the day of survey confirmed that calibration verification had not been performed on the Chem 8 panel every 6 months since 1/14 /20.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS) database proficiency testing report, and confirmation with TP #1 at 3:30 pm on 4/21/21, the laboratory director failed to ensure the laboratory was enrolled and participated in an HHS approved proficiency testing (PT) program for the Chem 8+ panel (categorized as non-waived on 1/14/2020) performed on the Abbott i-Stat Meter for 2020 and 2021. Findings include: 1. Review of the CMS database proficiency testing report revealed no scores for Chem 8+ (Sodium, Potassium, Chloride, CO2, BUN, Creatinine, Glucose, and Calcium) for years 2020 or 2021. 2. Review of the laboratory proficiency records since installation of the Abbott i-Stat meter on 1/14/2020 through the day of survey revealed no evidence of proficiency testing performed on the i-Stat Chem 8+ cartridge. 3. Interview with TP #1 at 3:30 pm on the day of survey confirmed the laboratory did not enroll in proficiency for the Chem 8+ panel for the years 2020 or 2021.