Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1004954	09/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bhs Physicians Network	1626 E Common Street, New Braunfels, TX	

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
D0000	Noted deficiency and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 laboratory's records for the Quidel Triage analyzer from 2022 and 2023, and staff interview, it was revealed the laboratory failed to have

	documentation of performing calibration verifications for CKMB, Troponin, and Myoglobin every six months. The findings include: 1. A review of the laboratory's records from 2022 and 2023 (as of the day of the survey) revealed the laboratory performed CKMB, Troponin, and Myoglobin testing on the Triage analyzer. 2. Further review of the records revealed the laboratory failed to have documentation of performing calibration verification every six months for each of the tests in 2022 and 2023 (0 of 3 required times). 3. The laboratory was asked to provide documentation of calibration verification being performed. No documentation was provided. 4. An interview with the technical consultant on 09/25/2023 at 11:30 am in the break room revealed the facility had not performed calibration verification for CKMB, Troponin or Myoglobin. She stated calibration verification was performed on the waived method of BNP. This confirmed the findings.