Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1099480	05/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Center For Pain Of Montgomery , Pc, The	448 St Lukes Drive, Montgomery, 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 Mindray BS-480 calibration records, a review of Mindray BS-480 quality control (QC) records, and an interview with the Technical Supervisor, the laboratory failed to perform calibration verification procedures at least every six months. This was noted from the date of the previous survey, 9/20/2022, to the date of the current survey, 5/21/2024. The findings include: 1. A review of Mindray BS-480 calibration data revealed only two calibration factors run at time of calibration for

	Amphetamine, Benzodiazepines, Cocaine, Methadone, Opiates, Oxycodone, Cannabinoids, Phencyclidine (PCP), Barbiturates, Methylenedioxymethamphetamine (MDMA), Creatinine, Oxidants, and Specific Gravity. 2. A further review of Mindray BS-480 QC records revealed only two levels of controls were performed each day of patient testing. No evidence of three levels of controls ran more than once daily was available for review. 3. During an interview on 5/22/2024 at 10:00 AM, the Technical Supervisor confirmed the above findings.