Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0306704	07/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Premier Medical Group	490 Dunlop Lane, Clarksville, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's procedure for calibration verification, the manufacturer operator's manual for the Tosoh G8 instrument, the manufacturer package inserts for the Siemens Dimension EXL200 instrument, laboratory records, and interview with technical consultant number two, the laboratory failed to follow procedure for calibration verification when they did not perform calibration verification using a low, mid and high value that spanned the reportable range for the hemoglobin A1c, sodium, potassium, chloride and triglyceride analytes in 2016, 2017, and 2018. The findings include: 1. Observation of the laboratory on July 17, 2018 at 8:15 am revealed the Tosoh G8 instrument in use for patient testing for hemoglobin A1c and the Siemens Dimension EXL200 in use for patient testing for general chemistry. 2. Review of the laboratory's procedure for calibration verification revealed the following: Calibration verification is used to verify the calibration is valid through the reportable range for the analyte and is performed every six months using a low, mid, and high level standard. 3. Review of the manufacturer operator's manual for the Tosoh G8 instrument revealed that calibration for the hemoglobin A1c analyte is performed using a two-point calibration. 4. Review of the Siemens Dimension EXL 200 manufacturer's package insert for the sodium, potassium, and chloride analytes revealed that calibration is performed using a two point calibration. 5. Review of the Siemens Dimension EXL 200 manufacturer's package insert for the triglyceride analyte revealed typical calibrator levels of 120, 240, and 485 mg/dL and a measurement range of 15-1000 mg/dL. 6. Review of

	laboratory records revealed there were no documents available documenting calibration verification using a low, mid, and high standard to verify the calibration through the reportable range of the test system for the hemoglobin A1c analyte on the Tosoh G8 instrument and the sodium, potassium, chloride and triglyceride analytes on the Siemens Dimension EXL 200 instrument in 2016, 2017, and 2018. 7. Interview with technical consultant number two on July 17, 2018 at 4:00 pm confirmed the laboratory failed to follow procedure for calibration verification for the hemoglobin A1c analyte performed on the Tosoh G8 instrument and the sodium, potassium, chloride and triglyceride analytes performed on the Siemens Dimension EXL 200 instrument when it did not perform calibration verification to include at least a low, mid and high standard that covered the reportable range of the instruments in 2016, 2017, and 2018.