Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305789	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Premier Medical Group, Inc	3701 Dauphin Street Allergy Dept 2nd Floor, Mobile, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the Thermo Scientific Phadia 250 Product information sheet, the temperature logs in the Allergy Laboratory, the patient log and an interview with Testing Personnel 2 (TP2), the laboratory failed to ensure environmental parameters specified on the log aligned with the manufacturer's operational requirements in the room where the Thermo Scientific Phadia was utilized for patient testing. The surveyor noted the RT recorded were below the manufacturer's established limits of 64.4-89.6 degrees Fahrenheit for 29 out of the 30 days in August 2024. The findings include: 1. A review of the Thermo Scientific Phadia 250 Product information sheet revealed operational environmental requirements of 18-32 degrees Celsius (64.4-89.6 degrees Fahrenheit). However, the temperature logs specified an acceptable RT range of 55-95 degrees F. 2. Due to an inaccurate acceptable range on the log, the Thermo Scientific Phadia 250 was utilized 29 days in August 2024 when RT's were 60-63 degrees F, temperatures below the manufacturer's required environmental specifications. 3. The patient testing logs revealed 345 patient samples were

	performed when the RT was below the manufacturer's acceptable operational range. 4. TP2 confirmed the above findings during the exit conference on 11-04-2025 at 11: 51PM.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on reviews of the Thermo Scientific Phadia 250 Quality Control (QC) logs, the patient test logs and an interview with the Testing Personnel 2 (TP2), the laboratory failed to ensure four levels of QC, (Low, Medium, High and Negative) were performed and documented each day of patient testing. The surveyor noted no QC was documented for three of the 31 days in March 2024. The findings include: 1. A review of the Thermo Scientific Phadia 250 QC logs revealed the laboratory failed to document the required QC prior to patient testing from March 13-15, 2024. 2. A review of the patient test log revealed 1,050 patient samples were performed during the three days without QC. 3. TP2 confirmed the above findings during the exit conference on 11-04-2025 at 11:51 AM.