Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2266771	03/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Freedom Pathology, Llc	4849 Paulsen Street, Suite 212, Savannah, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on March 10, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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: A tour of the laboratory facility confirmed that the laboratory failed to monitor room temperature and humidity for the rooms in which testing equipment was in use to assure accurate testing operations. THE FINDINGS INCLUDE: 1. A tour of the laboratory confirmed that room temperature and humidity were not monitored in areas in which analyzers were in use for patient testing. 2. A tour of the laboratory revealed the following analyzers in the laboratory with manufacturer established operating environment requirements in unmonitored environments: a. Tisue-Tek Prisma/ Film with the following operating environment requirements: Temperature = 10C - 40C and Relative Humidity = 30% - 85% non-condensing; b. AccuCut SRM with the following operating environment requirements: Temperature = 10C - 40C and Relative Humidity = 10% - 80% non-condensing; c. Tissue-Tek TEC with the following operating environment requirements: Temperature = 10C - 35C and

	Relative Humidity = 30% - 85% non-condensing; d. Leica Bond-Max with the following operating environment requirements: Temperature = 5C - 35C and Relative Humidity = 10% - 80% non-condensing; e. Tissue-Tek VIP with the following operating environment requirements: Temperature = 10C - 40C and Relative Humidity = 30% - 85% non-condensing; f. Olympus BX48 Microscope with the following operating environment requirements: Temperature = 5C - 40C and Relative Humidity = 80% for temperatures up to 31 C, decreasing linearly through 70% at 34 C, 60% at 37 C, to 50% relative humidity at 40 C; and g. KD-TH II Tissue Flotation System with the following operating environment requirements: Temperature = 0C - 40C and Relative Humidity ? 80%. 3. An exit interview, with Laboratory director and General Supervisor, on March 10, 2026, at 1:45pm confirmed that the laboratory failed to monitor room temperature and humidity for the rooms in which testing equipment was in use, for patient testing, to assure accurate testing operations.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A review of 2024 - 2026 Maintenance Records confirmed that laboratoryfailed to perform maintenance as required by the manufacturer. THE FINDINGS INCLUDE: 1. A review of 2024 - 2026 Maintenance Records revealed that the required maintenance performance documentation for the following analyzers/ equipment was not available for the following: a. Aries Filterworks Vega 30 & 60 GPH Deionizer System - no maintenance documentation b. PMT Scientific Air Filtration System - no maintenance documentation c. Olympus BX43 Microscope - no maintenance documentation d. Reagent Storage Refrigerator - initial validation records prior to use and annual maintenance was not in available 2. An exit interview, with Laboratory Director and General Supervisor, on March 10, 2026, at 1:45pm confirmed that the laboratory failed to perform maintenance as required by the manufacturer.