Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2286019	(X3) Date Survey Completed 04/17/2024
Name of Provider or Supplier Sagis, Pllc	**Street Address, City, State** 2341 Jt Ottinger Rd, Westlake, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 direct observation, review of manufacturer's instruction manual, laboratory records, and confirmed in staff interview, the laboratory failed to monitor temperature and humidity requirements for the microscope, located in the laboratory director's office for six of six months in 2023 and four of four months in 2024. Findings included: 1. During a tour of the laboratory director's office on 04/17/2024 at 1:25 pm, the surveyor observed the Olympus BX46 Microscope (Serial #2f40159) on the desk. The microscope was used to perform slide reviews for histopathology diagnostic testing. 2. Review of Olympus CX46 Microscope instruction manual revealed: "BX53 /BX43/BX46 SPECIFICATIONS Operating Environment ... Ambient temperature: 5 to 40C (41 to 104F) Maximum relative humidity: 80% for temperatures up to 31C (88F)" 3. Review of the laboratory records for 2023 and 2024 revealed no documentation of temperature or humidity monitoring for the Olympus CX43 Microscope. The laboratory was asked to provide documentation, and none was

	provided. 4. During an interview on 04/17/2024 at 1:25 pm, the Laboratory Director was asked if temperature and humidity were monitored and documented, and she stated "No". This confirmed the above findings. Word Key: C- Celsius F- Fahrenheit