

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2306649	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier Sagis, Pllc	Street Address, City, State 1315 St Joseph Pkwy, Ste 1208, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the manufacturer's instructions, the laboratory's records from 08/21/2024 to 10/30/2024, and confirmed in an interview, the laboratory failed to monitor the ambient temperature and humidity for 71 of 71 days from 08/21/2024 to 10/30/2024. The findings were: 1. In an interview on 10/30/2024 at 09:40 am in the pathologist's office, the director of Quality and Compliance confirmed the laboratory started date was August 21,2024. 2. The surveyor's direct observation on 10/30/2024 at 10:15 am revealed the pathologist read slides used OLYMPUS BX43 microscope. 3. Review of the manufacturer's instruction titled OLYMPUS INSTRUCTIONS BX43 SYSTEM MICROSCOPE (Printed in Japan on May 07, 2010 D00-02) on page 31 revealed "8. Operating environment -Ambient temperature 5 to 40C (41 to 104F) -Maximum relative humidity 80% for temperatures to 31C (88F), decreasing linearly through 70% at 34C (93F), 60% at 37C (99F), to (104F), to 50% relative humidity at 40C (104F). 4. Review the laboratory's records from 08/21/2024 to 10/30/2024 revealed no documentation of ambient temperatures</p>

and humidity for 71 of 71 days. 5. In an interview on 10/30/24 at 10:42 am in the pathologist's office, the director of Quality and Compliance confirmed the above finding. Key: C=Celsius F- Fahrenheit