Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0962326	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sagis	4582 N 1st Ave Ste 120, Tucson, AZ	

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) 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 review of the manufacturer's specified environmental conditions listed in the instrument user manual, lack of humidity logs presented for review and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity reading where the Ventana HE600 instrument is utilized for processing patient specimens under the sub-specialties of Endocrinology. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology, with an approximate annual test volume of 40,000. The laboratory uses the Ventana HE600 automated H & E stainer to stain patient slides. 2. The instrument user manual indicates a relative ambient humidity range of 10-80% is required while the instrument is in operational mode. 3. No documentation was presented for review during the survey to indicate the laboratory was monitoring and documenting the humidity of the laboratory where the instrument is used in conjunction with patient testing. 4. The facility personnel confirmed that the humidity of the laboratory was not monitored and documented.