Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2044865	04/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sagis	1033 La Posada Dr Ste 306, Austin, 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 surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of test reports, quality control (QC) records, query, and interview, the laboratory failed to document the positive and negative reactivity to ensure predictable staining characteristics for the immunohistochemical (IHC) stains used in its histopathology and dermatopathology interpretations for one of six test reports with IHCs and/or special stains reviewed from January 2023 - March 2024. Finding follow. A. Review of six test reports from 01/12/2023 - 03/07/2024 with IHCs or special stains showed one report, Accession #SD23-003325 reported 1/12/2023, was missing the comment documenting the performance of the quality control on the test report (which represented the documentation of quality control for the IHCs and special stains). The IHC panel performed for Accession #SD23-003325 included the following stains: 1. MSH2 (Mismatch Repair Protein) (79H11) 2. MLH1 (Mismatch Repair Protein) (ES05) 3. MSH6 (Mismatch Repair Protein) (EP49) 4. PMS2 (MRQ-28) B. Review of a query for the IHC panel (above) identified 33 cases received between 01/30/2022 - 04/13/2023 were impacted. C. Interview on March 3, 2024 at 1100 hours the Laboratory Director confirmed the findings at (A), and acknowledged

	he was just informed of the problem that one of the panels did not populate the control comment on the test report. Interview on March 3, 2024 at 1315 hours the Laboratory Director acknowledged the problem was discovered by an LIS employee on 04/11 /2023 and corrected on 04/28/2023 and confirmed findings at (B). D. Review of the CMS-116 showed the laboratory performed approximately 129,000 (total blocks, special stains and IHCs) tests per year. KEY: LIS = Laboratory Information System
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of test reports, quality control (QC) records, query, laboratory's policy and procedure, and interview, the laboratory failed to follow its written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems for 11 of 11 months reviewed (refer to D5601). Finding follow. A. Review of the laboratory's policy and procedure titled Quality Assurance (QA), adopted 06/04/2018, under Ongoing Assessment stated, "Each of the laboratory's quality systems will undergo assessment on a regular basis to maintain and improve laboratory performance and services. This assessment includes the following practices: ...The Laboratory Director or an appropriate, designated staff member will conduct meetings with all relevant staff every 6 months to communicate the results of corrective action, QC (quality control), and QA reviews and to address any concerns affecting laboratory performance. Additional staff meetings will be conducted to address any concerns or issues requiring more immediate attention." B. On March 3, 2024 at 1100 hours the Laboratory Director acknowledged he was just informed [during the survey] of the problem that one of the panels did not populate the control comment on the test report, and confirmed there was no QA documentation for the issue. On March 3, 2024 at 1315 hours the Laboratory Director acknowledged the problem was discovered by an LIS employee on 04/11/2023 and corrected on 04/28/2023 (elapsed time 11 months to date).