Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0480592	06/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Surgi Center	8230 Walnut Hill Ln Suite 808, Dallas, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory proficiency testing (PT) records, and confirmed in staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for histopathology slide interpretations (MOHs) for 2020. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a policy for performing proficiency testing. 2. Review of laboratory records revealed the laboratory performed histopathology slide interpretations using hematoxylin and eosin (H&E) stains and immunohistochemical (IHC) stains. Further review of proficiency testing records in 2020 revealed the

	laboratory performed twice annual accuracy assessments for the IHC slides but failed to perform twice annual accuracy assessments for H&E slides. 3. During an interview on 06/16/2021 at 10:25 am, the histotechnician confirmed the above findings.
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 manufacturer's instructions, environmental logs, and confirmed in interview, the laboratory failed to document and monitor the humidity of the cryostats for 12 of 12 months in 2020 and 6 of 6 months in 2021. Findings: 1. Review of Leica CM1510S operator's manual revealed: "3. Instrument components and specifications 3.2 Technical data ... All specifications related to temperature are based on ambient temperature of +22C and maximum air humidity of 60%!" Review of the Leica CM1520 operator's manual revealed: "3. Technical Data ...All specifications related to temperature of the cooling unit are valid only for an ambient temperature of 22C and a relative humidity of no more than 60%." 2. Review of the environmental logs revealed there was no documented evidence for humidity in 2020 and 2021. The laboratory failed to monitor and document the humidity of the cryostats. 3. During an interview on 06/16/2021 at 11:45 am, histotechnician stated that humidity was not monitored or documented for the cryostats in 2020 and 2021, confirming the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS (Center for Medicaid & Medicare Services) 116 form, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain. Findings: 1. Review of laboratory policy "H&E Staining Procedure for Frozen Tissue Sections" revealed: "Quality Control: Stains are filtered daily and grossly examined for any evidence of contaminant or precipitates. Solutions are changed as follows: hematoxylin and eosins stains are changed weekly, alcohols and xylenes are rotated daily." The procedure failed to define the staining characteristics for intended reactivity for the H&E stain. Review of laboratory policy "H&E Staining Procedure for Permanent Tissue Sections" revealed: "Quality Control: Stains are filtered daily

	and grossly examined for any evidence of contaminant or precipitates. Solutions are changed as follows: hematoxylin and eosins stains are changed weekly, alcohols and xylenes are rotated daily." The procedure failed to define the staining characteristics for intended reactivity for the H&E stain. 2. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory had an annual test volume of 7,200 histopathology cases. 3. During an interview on 06/16/2021 at 12:15 pm, the histotechnician confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records, and confirmed in staff interview, the technical supervisor failed to evaluate and document annual competency assessments for 1 of 3 testing persons (TP-2) responsible for high complexity testing in 2020. Findings: 1. Review of laboratory policies revealed the laboratory failed to have a policy for performing competency assessments. 2. Review of personnel records revealed the technical supervisor failed to evaluate and document annual competency assessment for TP-2 in 2020. 3. During an interview on 06/16 /2021 at 10:25 am, the histotechnician confirmed the above findings.