Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2093707	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Texas Health Surgicenter Addison Dba	17980 Dallas Parkway, Suite 100, 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	The laboratory director was at the entrance conference conducted 10/22/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the laboratory director on 10/22/2019. 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.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review the laboratory's procedure manual, Hematoxylin & Eosin (H&E)

	stain records, and in interview with staff, the laboratory failed to ensure their policies /procedures included defined intended reactivity of H&E stain to ensure predictable staining characteristics. Findings included: 1. Review of the laboratory's "Quality Control Policy" stated, "It is the responsibility of testing personnel (pathologists) to monitor and record the quality of the rapid H&E stains each day of use (on days when no patient testing is performed, QC of the rapid H&E stain is not required). The stain quality/acceptability is recorded in the Frozen Section Log. QC of the rapid H&E stain must be analyzed with the first patient sample being tested. No patient result may be reported until such time as the rapid H&E stain quality is determined to be acceptable (i.e. satisfactory or good)." Review of the "RAPID HEMATOXYLIN AND EOSIN STAIN" procedure stated, "VI. QUALITY CONTROL: Testing personnel (pathologists) monitor the quality of the rapid H & E frozen section stains each day of use. Stains should be changed as needed upon use, or at the first sign of deterioration of stain quality. The stain quality/acceptability is recorded in the frozen section log. In addition, specific errors and problems may be recorded in an exception report where corrective measures are stated. An unacceptable stain/quality record is grounds for remedial action." The written policy/procedure did not include defined intended reactivity of H&E stain to ensure predictable staining characteristics. 2. Review of "FROZEN SECTION LOG'S" from 08/01/2018 through 10/14/2019 included 54 patient cases with documentation of "STAIN QUALITY" each time of H&E stain use. Intended reactivity of H&E stain was not documented to ensure predictable staining characteristics. Refer to D5473. 3. During an interview on 10/22 /2019 at 11:15 am, the laboratory director confirmed the written policy/procedure did not include defined intended reactivity of H&E stain.
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, temperature logs, and in interview with staff, the laboratory failed to monitor and document humidity to ensure operating conditions were met for the Leica CM1850 cryostat for 12 of 12 months in 2018 and 10 of 12 months in 2019 (01/2018 through 10/2019). Findings included: 1. Review of the Leica CM1850 operator's manual (manufacturer's instructions) stated, "4.1 Site requirements: Air humidity must not exceed 60% High room temperatures and excessive air humidity affect the cooling capacity of the cryostat." 2. Review of temperature logs for the frozen section room from 01/2018 through 10/2019 did not include a defined criteria for humidity and did not include documentation of humidity. The laboratory did not monitor and document humidity to ensure operating conditions were met for the Leica CM1850 cryostat. 3. During an interview on 10/22/2019 at 11: 15 am, the laboratory director confirmed humidity was not being monitored or documented in the frozen section room.
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 the laboratory's procedure manual, Hematoxylin & Eosin (H&E) stain records, and in interview with staff, the laboratory failed to ensure documentation of H&E intended reactivity to ensure predictable staining characteristics from 08/2018 through 10/2019. Findings included: 1. Review of the laboratory's "Quality Control Policy" stated, "It is the responsibility of testing personnel (pathologists) to monitor and record the quality of the rapid H&E stains each day of use (on days when no patient testing is performed, QC of the rapid H&E stain is not required). The stain quality/acceptability is recorded in the Frozen Section Log. QC of the rapid H&E stain must be analyzed with the first patient sample being tested. No patient result may be reported until such time as the rapid H&E stain quality is determined to be acceptable (i.e. satisfactory or good)." Review of the "RAPID HEMATOXYLIN AND EOSIN STAIN" procedure stated, "VI. QUALITY CONTROL: Testing personnel (pathologists) monitor the quality of the rapid H & E frozen section stains each day of use. Stains should be changed as needed upon use, or at the first sign of deterioration of stain quality. The stain quality/acceptability is recorded in the frozen section log. In addition, specific errors and problems may be recorded in an exception report where corrective measures are stated. An unacceptable stain/quality record is grounds for remedial action." The written policy/procedure did not include defined intended reactivity of H&E stain to ensure predictable staining characteristics (Refer to D5403). 2. Review of "FROZEN SECTION LOG'S" from 08/01/2018 through 10/14/2019 included 54 patient cases with documentation of "STAIN QUALITY" each time of H&E stain use. Intended reactivity of H&E stain was not documented to ensure predictable staining characteristics, as follows (random sampling): Patient #1 - 08/01/2018 - stain quality "ok" Patient #2 - 08/21/2018 - stain quality "good" Patient #3 - 09/18/2018 - stain quality "GOOD" Patient #4 - 09/25/2018 - stain quality "ok" Patient #5 - 03/25/2019 - stain quality "Good" Patient #6 - 06/11/2019 - stain quality "ok" Patient #7 - 06/25/2019 - stain quality "Good" Patient #8 - 08/26/2019 - stain quality "Good" Patient #9 - 09/23/2019 - stain quality "Good" Patient #10 - 10/14/2019 - stain quality "ok" (see attached alias list) 3. During an interview on 10/22/2019 at 11:15 am, the laboratory director confirmed intended reactivity of H&E stain was not documented to ensure predictable staining characteristics nor did the written policy/procedure include defined intended reactivity of H&E stain.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's procedure manual, temperature charts, frozen section log, and in interview with the staff, the laboratory failed to document corrective action taken when the frozen section room temperature was out of its acceptable range for 2 of 21 documented days in 03/2019 (03/04/19 and 03/05/19). Findings included: 1. Review of the laboratory's "Quality Control Policy" stated, "Responsibilities: It is the responsibility of staff of Texas Health Surgery Center Addison to record temperatures in the Temperature Log, and notify the Laboratory Director if temperatures are out of the ranges on the log sheet. QUALITY CONTROL FAILURES: In the event of unacceptable temperatures, staff of the Texas Health Surgery Center Addison should notify the Laboratory Director so that correction action can be taken." 2. Review of the 03/2019 frozen section room temperature log included the defined criteria 15C to 30C. The following days were out of the defined criteria of 15 to 30C and corrective action was not documented: 03/04/2019: 13.3C; Patient #11 was processed for a frozen section 03/05/2019: 13.8C (no patients for frozen section) (see attached alias list) 3. During an interview on 10/22/2019 at 11:00 am, the laboratory director reviewed the above findings and confirmed the facility staff did not notify him of the out-of-range temperature to take and document corrective action.