Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1102343	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Methodist Hospital,The	6550 Fannin St, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 the laboratory records from 2017 and 2018 and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 2 of 2 tests in 2017 and 1 of 2 tests in 2018. a) Mohs b) grossing Findings were: a) Mohs 1. A review of laboratory testing records from 2017 and 2018 revealed no documentation of the laboratory verifying the accuracy for the Mohs test for 2017. b) grossing 2. A review of laboratory testing records from 2017 revealed no documentation of the laboratory verifying the accuracy for grossing in 2017. A review of laboratory testing records from 2018 revealed 1 of 2 documentation of the laboratory verifying the accuracy for grossing for 2018. No documentation was provided for the 2nd annual accuracy assessment for 2018. 3. An interview with the manager on 5/23/19 at 1115 hours in the break room confirmed the above findings.
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 policy, review of the cryostat maintenance records, and confirmed in interview, the laboratory failed to document the corrective actions when the temperature of the cryostat was outside of the specified acceptable range per the laboratory policy. Findings were: 1. Review of the laboratory policy Frozen Section workroom Setup under cryostat revealed "check cryostats temperature before first case, and note the actual cryostat temperature in the log book. Temperature should be in -25C to -35C range when in use. If out of range note problem and solution in the maintenance log book." 2. Random review of the cryostat maintenance records from 2017 to 2019 records revealed 8 of 40 days with temperature outside of the acceptable range of -25C to -35C. Date Temperature 10/30/17 -21C 11/06/17 -21C 11/13/17 -21C 11/20/17 -21C 10/15/18 -21C 08/27/18 -21C 08/20/18 -21C 06/04/18 -21C 3. Review of the patient test logs for the above dates revealed the laboratory performed patient testing with the temprature outside of the acceptable range and no documentation of the corrective action per the laboratory policy. Date Patient ID 10/30 /17 17G275 11/06/17 17G286 11/13/17 17G301 11/20/17 17G307 10/15/18 18G317 08/27/18 18G299 08/20/18 18G278A 06/04/18 18G188 4. An interview with the manager on 5/23/19 at 1105 hours in the break room confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory director failed to establish and maintain a quality assessment program for 2017 and 2018. Findings were: 1. Review of the laboratory records available revealed no documentation of a quality assessment policy or records for 2017 and 2018. 2. An interview with the manager on 5/29/19 at 1105 hours in the break room confirmed the above findings. He acknowledged that the laboratory should have policies and document a quality assessment program.
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 the laboratory records and confirmed in interview, the technical supervisor failed to document an annual competency for 1 of 2 testing person (TP) for

	2017. Findings were: 1. Review of the laboratory policy under Competency Assessment revealed "laboratory personnel will be evaluated and assessed on an annual basis as to their competency in cutting tissue, and the various staining procedure." 2. Review of the 2017 and 2018 personnel records revealed no documentation of the 2017 competency for testing person 1. 3. An interview with the manager on 5/23/19 at 1110 hours in the break room confirmed the above findings.