Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1102343	04/20/2021
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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory maintenance policy for the cryostat instrument in the procedure manual, maintenance logs from 2020 to 2021, and an interview revealed the laboratory failed to follow the its lab policy to defrost instruments every 6 months in 2020. The findings were: 1. Review of the laboratory Maintenance policy in procedure manual revealed "Every 6 months defrost" for the instruments under Maintenance section. 2. Review of the maintenance log for cryostat#1 from 1/6/20 to 4 /19/21 revealed no documentation of defrost maintenance for the instrument every 6 months. 3. Review of the maintenance log for cryostat#2 from 10/12/20 to 4/19/21 revealed no documentation of defrost maintenance for the instrument every 6 months. 4. Review of CMS 116 revealed the annual test volume of cryosectioning is 321. 5. An interview with the laboratory manager on 4/20/21 at 10:45am in the breakroom confirmed the above findings.
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 control slides policy in the laboratory procedure manual, H & E stain quality QC logs in 2020, and an interview revealed the laboratory failed to document H & E stain quality QC by the testing personnel (TP) for 4 of 10 days reviewed. The findings were: 1. Review of Control Slides policy in the procedure manual revealed: "it is checked by the histotechnician first and by the surgeon /pathologist when he/she becomes available. The slide check-off sheet will be completed by the histotech and M.D.." 2. Review of H & E stain quality QC logs from 1/7/19 to 4/19/21 revealed the laboratory failed to document H&E stain quality for 4 of 10 days. 3/16/20 6/22/20 10/26/20 12/28/20 3. Review of CMS 209 signed by the laboratory director revealed the pathologist is the same as the TP. 4. Random review of patient reports from 3/16/20 to 12/28/20 revealed 8 patient were performed on the above dates with no documentation of the stain quality controls. 3/16/20 Patient case# 103 3/16/20 Patient case# 104 6/22/20 Patient case# 133 6/22/20 Patient case# 134 10 /26/20 Patient case# 239 10/26/20 Patient case# 240 12/28/20 Patient case# 319 12/28 /20 Patient case# 320 5. An interview with the laboratory manager in the breakroom on 4/20/21 at 1225 confirmed the above findings.
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 the laboratory's policies in procedure manual, and an interview revealed the laboratory quality assessment policy failed to monitor, assess, and correct problems in analytical systems. Refer to D5401 and D5601