Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1102343	10/28/2024
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	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. Standard level deficiencies were cited.
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 a review of the laboratory's policies, the laboratory's accuracy assessment records for 2023, and staff interview, the laboratory failed to have documentation of performing two of two twice annual accuracy assessments for Mohs slide interpretations in 2023. Findings include: 1. A review of the laboratory's policy titled 'Mohs Laboratory Procedure' revealed the following: "Proficiency by a consulting dermatopathologist or another Mohs surgeon will be done two times a year." 2. A review of the laboratory's accuracy assessment records revealed the laboratory failed to have documentation of performing 2 accuracy assessments for Mohs slide interpretations in 2023. 3. In an interview on 10/29/24 at 10:25 a.m. in the break room, after review of the records, the manager of operations confirmed the above findings.
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 a review of the laboratory's policies, a random review of patient's histopathology slides from November 2023 to August 2024, and staff interview, the laboratory failed to follow its policy for the of labeling slides for three of seven patient's histopathology slides reviewed. Findings include: 1. A review of the laboratory's policy titled 'Labeling of Frozen Section Slides' revealed the following: "Slides are to be labeled before frozen sections are cut - Information to be written with a slide marking pen on the frosted end of the slide must be obtained from the Digital photo that was delivered with the tissues. - Line 1 - Surgery Accession (Case) # and lesion designation (A, B, etc.) - Line 1 - Patient Name: Last name, First initial (first slide of each case)" 2. A random review of patient slides from November 2023 to August 2024 revealed the following patient's slides were not labeled as required per the laboratory's policy: Accession number: 23G427 Date: 11/21/23 - slide did not include the patient's first initial Accession number: 24G070 Date: 2/26/24 - slide did not include the patient's first initial Accession number: 24G218A Date: 8/5/24 - slide did not include the patient's first initial 3. In an interview on 10/29/24 at 10:35 a.m. in the break room, after review of the records, the manager of operations confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the Weekly Microscope Maintenance Records, patient test records, and staff interview, the laboratory failed to have documentation of performing the weekly microscope maintenance procedures for three of forty two days from October 2023 to October 2024. Findings include: 1. A review of the laboratory's policy titled 'Microscope Care' revealed the following: "Weekly Maintenance: a. Wipe down microscope with alcohol wipes. To remove fingerprints or oil, wipe with gauze moistened with xylene or mixture of ether (70%) and alcohol (30%). b. Clean all lenses with lens paper." 2. A review of the Weekly Microscope Maintenance Records from October 2023 to October 2024 revealed the laboratory failed to have documentation of performing the weekly microscope maintenance procedures for the following 3 days: 10/9/23 11/21/23 10/21/24 3. A review of patient test records revealed the following patients were tested on days when the weekly microscope maintenance procedures were not documented: Date tested: 10/9/23 Patient Case Numbers: 23G346, 23G347, 23G348, 23G349, 23G350, 23G351, 23G352, 23G353, 23G354, 23G355, 23G356 Date tested: 11/21/23 Patient Case Numbers: 23G417, 23G418, 23G419, 23G420, 23G421, 23G422, 23G423, 23G424, 23G425, 23G426, 23G427 Date tested: 10/21/24 Patient Case Numbers:

	24G281, 24G282, 24G283, 24G284, 24G285, 24G286, 24G287, 24G288 4. In an interview on 10/28/24 at 10:50 a.m. in the break room, after review of the records, the manager of operations confirmed 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 a review of laboratory's policies, the laboratory's Slide Check- Off Sheets, patient test records, and staff interview, the laboratory failed to document the intended reactivity of the Toluidine blue stain for MOHS histopathology slides each day of use for three of eighteen days from July to November 2023. Findings include: 1. A review of the laboratory's policy titled 'Control Slides' revealed the following: "The first frozen section of the day (tumor tissue from the first lesion) serves as the stain control slide. 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 MD. Any needed changes or adjustments are made." 2. A review of the laboratory's Slide Check- Off Sheets from July to November 2023 revealed the laboratory failed to have documentation of the intended reactivity for the Toluidine blue stain on the following 3 days: 7/31/23 8/7/23 11/27/23 3. A review of patient test records revealed the following patients were tested on days when the intended reactivity of the Toluidine blue slide was not documented: Date tested: 7/31/23 Patient Case Numbers: 23G295, 23G296, 23G297, 23G298, 23G299, 23G300, 23G301, 23G302, 23G303, 23G304, 23G305 Date tested: 8/7/23 Patient Case Numbers: 23G306, 23G307, 23G308, 23G309, 23G310, 23G311, 23G312, 23G313, 23G314, 23G315 Date tested: 11/27/23 Patient Case Numbers: 23G428, 23G429, 23G430, 23G431, 23G432, 23G433, 23G434, 23G435, 23G436, 23G437 4. In an interview on 10/28/24 at 10:40 a.m. in the break room, after review of the records, the manager of operations confirmed the above findings.