

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1102343	<b>(X3) Date Survey Completed</b> 12/12/2022
<b>Name of Provider or Supplier</b> Methodist Hospital,The	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>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 July 2021 to December 2022, and staff interview, it was revealed that the laboratory failed to follow its policy for labeling slides for one of five 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 labelled 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 July 2021 to December 2022 revealed the following patient's slides were not labeled as required per the laboratory's policy: Accession number: 21G214 Date: 7/19/21 - slide did not include the patient's first initial 3. An interview with the manager of operations on 12 /12/22 at 9:55 a.m. in the break room, after review of the records, confirmed the above findings.</p>

## 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:

I. Based on a review of laboratory's policies, the laboratory's Slide Check- Off Sheets from March 2022 to November 2022, a review of patient test records, and staff interview, it was revealed that the laboratory failed to document the adequacy of the Toluidine Blue stain for Mohs histopathology slides each day of use for three of ten days reviewed from March 2022 to November 2022. Findings: 1. A review of the laboratory's policy titled 'Staining Procedures' revealed the following: "The routine stain for frozen sections in this Mohs surgery lab is Toluidine Blue, 0.5% aqueous. 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 M.D." 2. A review of the Slide Check - Off Sheets from March 2022 to November 2022 revealed a column for the pathologist to place a check mark, indicating the Toluidine Blue stain of the control slide was adequate for patient use. 3. Further review of the laboratory's Slide Check- Off Sheets revealed no documentation of the pathologist's check mark for the Toluidine Blue stain on the following 3 days: 3/21/22 11/14/22 11/21/22 4. A review of patient test records revealed the following patients were tested on days when the stain was not documented as adequate: Date 3/21/22 Patients: 22G080, 22G081, 22G082, 22G083, 22G084, 22G085, 22G086, 22G087, 22G088, 22G089, 22G090, 22G091 Date 11/14 /22 Patients: 22G304, 22G305, 22G306, 22G307, 22G308, 22G309, 22G310, 22G311, 22G312, 22G313 Date 11/21/22 Patients: 22G314, 22G315, 22G316, 22G317, 33G318, 22G319, 22G320, 22G321, 22G322, 22G323, 22G324, 22G325 5. An interview with the manager of operations on 12/12/22 at 9:55 a.m. in the break room, after review of the records, confirmed the above findings. II. Based on a review of laboratory's policies, the laboratory's Slide Check- Off Sheets, a review of patient test records, and staff interview, it was revealed that the laboratory failed to follow its policy by not documenting the histotechnician and the pathologist's check of the adequacy of the Toluidine Blue stain for Mohs histopathology slides each day of use for 10 of 48 days reviewed from July 2021 to December 2022. Findings: 1. A review of the laboratory's policy titled 'Staining Procedures' revealed the following: "The routine stain for frozen sections in this Mohs surgery lab is Toluidine Blue, 0.5% aqueous. 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 M.D." 2. A review of the Slide Check - Off Sheets from July 2021 to December 2022 revealed a column for the pathologist and a column for the histotechnician to place a check mark, indicating the Toluidine Blue stain of the control slide was adequate for patient use. 3. Further review of the laboratory's Slide Check- Off Sheets revealed no documentation of the pathologist's check mark for the Toluidine Blue stain on the following 10 days: 7/12/21 7/19/21 2/21/22 3/28 /22 4/4/22 10/3/22 11/7/22 11/12/22 11/28/22 12/5/22 4. A random review of patient test records revealed the following patients were tested on days when the stain was not

documented as adequate by the pathologist: Date 7/19/21 Patients: 21G214 Date 4/4/22 Patients: 22G092, 22G093, 22G094, 22G095, 22G096 Date 10/3/22 Patients: 22G283, 22G284, 22G285, 22G286, 22G287 Date 11/7/22 Patients: 22G294, 22G295, 22G296, 22G297, 22G298 Date 11/28/22 Patients: 22G326, 22G327, 22G328, 22G329, 22G330 Date 12/5/22 Patients: 22G337, 22G338 5. An interview with the manager of operations on 12/12/22 at 9:55 a.m. in the break room, after review of the records, confirmed the above findings.