

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1105542	<b>(X3) Date Survey Completed</b> 07/28/2022
<b>Name of Provider or Supplier</b> Texas Dermatology Specialists PLLC	<b>Street Address, City, State</b> 21800 Katy Freeway # 200, Katy, 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 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
<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 slides from 2021 and 2022, and staff interview, it was revealed that the laboratory failed to follow its policy for labeling slides for two of four patient's slides reviewed for 2021 and 2022. Findings include: 1. A review of the laboratory's policy titled 'Texas Dermatology Specialists- Katy Laboratory Manual' revealed the following: "Information to be written with a slide marking pen on the frosted end of the slide must be obtained from for MOHS Map that was delivered with the specimen. - Line 1- Surgery Accession (Case) #. - Line 2- Patient name: Last name, first name (first slide</p>

of case, initials are acceptable for additional slides). - Line 3- Location or site of lesion - Line 4- date, stage #, tissue #" 2. A random review of patient slides from 2021 and 2022 revealed the following 2 patient slides were not labeled as required per the laboratory's policy: KM21-149 - did not include the patient's first name - did not include the date KM21-98 - did not include the patient's first name - did not include the site of lesion 3. An interview with the MOHS histo tech on 7/28/22 at 1:20 p.m. in the break room, after review of the records, 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 Tissue Quality logs from February 2022 to July 2022, a review of patient test records, and staff interview, it was revealed that the laboratory failed to document the adequacy of the Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for 12 of 40 days reviewed from February 2022 to July 2022. Findings: 1. A review of the laboratory's policy titled 'Texas Dermatology Specialists- Katy Laboratory Manual' revealed the following: "Staining Procedures Purpose: To provide staining consistency The routine stain for frozen sections in this MOHS surgery lab is the Hematoxylin & Eosin. Control Slides Purpose: To confirm proper functioning of the automatic stainer, insure desired staining results." 2. A review of the Tissue Quality logs from February 2022 to July 2022 revealed a column for the pathologist to place a check mark, indicating the H&E stain of the QC slide was adequate for patient use. 3. Further review of the laboratory's Tissue Quality logs from February 2022 to July 2022 revealed no documentation of the pathologist's check mark for the H&E stain on the following 12 days: 2/3/22 2/10/22 2/11/22 2/17/22 2/18/22 2/24/22 2/25/22 7/1/22 7/7/22 7/8/22 7/14/22 7/15/22 4. A review of patient test records revealed the following patients were tested on days when the H&E stain was not documented as adequate: Date: 2/3/22 Patient Numbers: 51, 52, 53, 54, 55, 56 Date: 2/10/22 Patient Numbers: 57, 58, 59, 60, 61, 62, 63 Date: 2/11/22 Patient Numbers: 64, 65, 66, 67, 68, 69, 70 Date: 2/17/22 Patient Numbers: 71, 72, 73, 74, 75, 76, 77 Date: 2/18/22 Patient Numbers: 78, 79, 80, 81, 82, 83 Date: 2/24/22 Patient Numbers: 84, 85, 86, 87 Date: 2/25/22 Patient Numbers: 88, 89, 90, 91, 92 Date: 7/1/22 Patient Numbers: 244, 245, 246, 247 Date: 7/7/22 Patient Numbers: 248, 249, 250, 251, 252 Date: 7/8/22 Patient Numbers: 253, 254, 255 Date: 7/14/22 Patient Numbers: 256, 257, 258, 259 Date: 7/15/22 Patient Numbers: 260, 261, 262, 263, 264, 265 5. An interview with the MOHS histo tech on 7/28/22 at 1:35 p.m. in the break room, after review of the records, confirmed the above findings.