

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0888288	(X3) Date Survey Completed 09/21/2022
Name of Provider or Supplier Plano Dermatology Associates	Street Address, City, State 6100 Windhaven Parkway, Plano, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Southern Operations Branch-Dallas 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.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory procedure manual, patient test records, and confirmed in interview, the laboratory failed to ensure patient histopathology slides were labeled with the patient's full name or unique patient identifier for 15 of 15 slides in December 2021 and 19 of 19 slides in August and September (random sampling). The</p>

findings include: 1. Review of the laboratory's procedure manual Section V-6 page 13 revealed: "3.4.9 Laboratory technician will cut frozen sections and stain. Slides are labeled with number, full patient name and date." The laboratory procedure did not include labeling instructions for processing specimens with the same first and last name or birth date using unique patient identifiers to distinguish between specimens. 2. A random review of patient test records from December 2021 and August and September 2022 revealed 34 slides labeled with the patient's last name, first initial, date of service, and stage number. 3. During an interview on 09/21/2022 at 12:04 p.m., the Office Manager confirmed the above findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on review of the operator's guide, laboratory environmental logs, and confirmed in interview, the laboratory failed to accurately monitor and document Cryostat temperatures used to process patient specimens for 13 of 33 days in 2022 (June and July) for Leica Cryostat #7 and 14 of 15 days in July 2022 for Leica Cryostat #8. The findings include: 1. Review of the Leica Cryostat operator's guide revealed a frozen section range of -10C to -30C. 2. Review of laboratory environmental logs for the Leica Cryostat revealed the laboratory had an established acceptable temperature range for Cryostat #7 and Cryostat #8 as "-15 to -30 degrees". Note: the range was not defined in Celsius or Fahrenheit. 3. Further review of the laboratory's environmental logs for the Leica Cryostats from May to September 2022 revealed the following documented temperatures for Cryostat #7 and Cryostat #8 that were not within the defined range of -15 to -30 degrees: A. CRYOSTAT# 7; SERIAL# 2289 06/14/2022; Temperature: "28" 06/15/2022; Temperature: "28" 06/16/2022; Temperature: "28" 07/12/2022; Temperature: "28" 07/13/2022; Temperature: "28" 07/18/2022; Temperature: "28" 07/19/2022; Temperature: "28" 07/20/2022; Temperature: "28" 07/21/2022; Temperature: "28" 07/25/2022; Temperature: "28" 07/26/2022; Temperature: "28" 07/27/2022; Temperature: "28" 07/28/2022; Temperature: "28" B. CRYOSTAT# 8; SERIAL# 2287 07/05/2022; Temperature: "27" 07/06/2022; Temperature: "27" 07/07/2022; Temperature: "27" 07/11/2022; Temperature: "27" 07/12/2022; Temperature: "27" 07/13/2022; Temperature: "27" 07/18/2022; Temperature: "27" 07/19/2022; Temperature: "27" 07/20/2022; Temperature: "27" 07/21/2022; Temperature: "27" 07/25/2022; Temperature: "27" 07/26/2022; Temperature: "27" 07/27/2022; Temperature: "27" 07/28/2022; Temperature: "27" The laboratory failed to properly monitor and document Cryostat temperatures. 4. During an interview on 09/21/2022 at 10:49 a.m., the Office Manager confirmed the above findings.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation and confirmed in interview, the laboratory failed to ensure tissue marking dyes stored in secondary containers were labeled with proper identification and poured/expiration dates for 4 of 4 dyes. The findings include: 1. During a tour of the laboratory on 09/21/2022 at 12:37 p.m., the surveyor observed 4 unlabeled amber glass dropper bottles and 4 unlabeled transparent microtainers on the countertop. The laboratory failed to label the secondary containers with the name of the dye, lot numbers, and poured/expiration dates. Without proper labeling, the dyes could not be linked to their original containers. 2. During an interview on 09/21/2022 at 12:37 p.m., the Office Manager and Histotechnician confirmed the amber dropper bottles and transparent microtainers contained dyes for tissue marking. This confirmed the above findings.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation and confirmed in interview, the laboratory failed to ensure 5 of 5 tissue marking dyes were not expired when used in processing histopathology specimens. The findings include: 1. During a tour of the laboratory on 09/21/2022 at 12:37 p.m., the surveyor observed the following expired tissue marking dyes in a cabinet: Red Tissue Marking Dye Lot# 097214; Expiration: 2022-03-31 Black Tissue Marking Dye Lot# 099679; Expiration: 2022-05-31 Green Tissue Marking Dye Lot# 097194; Expiration: 2022-03-31 Blue Tissue Marking Dye Lot# 099682; Expiration: 2022-05-31 Black Tissue Marking Dye Lot#099679; Expiration: 2022-05-31 2. During an interview on 09/21/2022 at 12:37 p.m., the Office Manager confirmed the tissue marking dyes had exceeded their expiration date.

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 review of laboratory's procedure manual, Mohs logs, patient reports, and confirmed in interview, the laboratory failed to define and document the intended

reactivity of Hematoxylin & Eosin (H&E) stain quality control for Mohs histopathology slides each day of use for 21 of 21 days in December 2021 and 27 of 27 days in August and September 2022 (random review). The findings include: 1. Review of the laboratory procedure manual Section V-6 page 19 titled "6. Quality Control" revealed: "6.1.1 All slides, XXXXXXXXXX, and reports are available for review by laboratory accrediting agencies. 6.1.2 Reports from cases sent for consultation are maintained as part of the record 6.1.3 Reports of cases presented at conferences and scientific meeting and in scientific publications are maintained as part of the record 6.1.4 The laboratory participates in the reciprocal reading of slide with no other agencies 6.1.5 XXXXXXXXXX MODIFICATION AND UPDATES Paragraph 6.1.1: Omit paraffin blocks 07/19/1994 Paragraph 6.1.5: Omit existing sentence and add: The Frozen Section procedure will serve as control 07/19/1997 ... Paragraph 6.1.4 Changed to participate with ... for reciprocal reading of slides starts 01/01/2016" The procedure failed to define the staining characteristics for intended reactivity for the H&E stain. 2. A random review of Mohs logs from December 2021 and August and September 2022 revealed the logs did not include for each day of use, documentation of the intended reactivity for the H&E stain on the following days patients were tested and reported in 2021 and 2022: 2021 December: 1, 2, 3, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 20, 21, 22, 23, 27, 28, 29, 30 2022 August: 1, 2, 3, 4, 8, 9, 10, 11, 15, 16, 17, 18, 22, 23, 24, 25, 29, 30, 31 September: 1, 6, 7, 8, 12, 13, 14, 15 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. A random review of patient reports revealed no definition or documentation of intended reactivity to ensure predictable H&E characteristics. The following is a random sampling of patients that were tested and reported when quality control was not defined and documented: 12/30/2021 Case #: 2992, 2994, 2998, 3006 08/02/2022 Case #: 2039, 2057 08/08/2022 Case #: 2090, 2091 08/31/2022 Case #'s: 2318, 2332 09/15/2022 Case #'s: 2455, 2473 4. During an interview on 09/21/2022 at 11:20 a.m., the Office Manager and Medical Assistant confirmed the above findings.