

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0918958	(X3) Date Survey Completed 10/22/2020
Name of Provider or Supplier Us Dermatology Partners	Street Address, City, State 1213 Hermann Drive Suite 650, 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 at the entrance and exit conferences. The facility representative was 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.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: A. Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure aliquoted containers of multiple reagents were labeled to indicate identity, storage requirements and expiration dates to ink for grossing histopathology slides. The findings were: 1. Surveyor observation of marking dyes stored within the laboratory on 10/22/2020 at 0940 hours revealed dyes were stored in plastic containers on the bench top. The containers were not labeled with an expiration date or storage requirement, only the ink color. 2. An interview with the facility</p>

personnel on October 22, 2020 at 1025 hours in the laboratory confirmed the findings. She agreed that the aliquot container did not have any information further than the name of the reagent. B. Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to label 1 of 5 reagents located in the laboratory as to its contents, storage requirements, and expiration date to ink for grossing histopathology slides. The findings included: 1. Direct observation made by the surveyor on October 22, 2020 at 1025 hours in the Laboratory revealed 1 black bottle with black liquid. The bottle was not labeled with any identifying information. a. The content's identity could not be determined. b. The content's storage requirements could not be determined. c. The content's expiration dates could not be determined. 2. Random review of patient reports from September 23, 2020 to October 19, 2020, the laboratory performed Mohs testing on 10 patients when reagents were inked with an unlabeled reagent and expiration date. Date of Test Patient ID 09/23/2020 SS20-130636 09/29/2020 HST20-2214 10/06/2020 HST20-2596 10/12/2020 DAT20-46385 10//12/2020 DAT20 46522 10/13/2020 DAT20-46379 10/14/2020 D20-5735 10/14/2020 HST20-2324 10/15/2020 SS20-124012 10/19/2020 SD20-111276 2. An interview with the facility personnel on 10/22/2020 at 1025 hours in the laboratory confirmed the findings. She agreed the container was not labeled with the identifying ink storage and expiration date.

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 surveyor observations, review of patient reports from September 23, 2020 to October 19, 2020 and confirmed in interview of facility personnel, the laboratory failed to ensure expired items were not available for use in patient testing. The findings were: 1. Surveyor observation on October 22, at 0940 hours of dyes currently in use in the laboratory for making margins of Mohs slides , revealed the following 3 of 5 Tissue Marking Dyes were expired items: Surgipath Tissue Dye Marking Red Lot 120718 Expiration Date: 2019-12-07 Surgipath Tissue Dye Marking Blue Lot 04162015 Expiration Date: 2019-04 Surgipath Tissue Dye Marking Yellow Lot 08302017 Expiration Date: 2018-04 2. Random review of patient reports from September 23, 2020 to October 19, 2020, the laboratory performed Mohs testing on 10 patients when reagents were expired. Date of Test Patient ID 09/23/2020 SS20-130636 09/29/2020 HST20-2214 10/06/2020 HST20-2596 10/12/2020 DAT20-46385 10//12/2020 DAT20 46522 10/13/2020 DAT20-46379 10/14/2020 D20-5735 10/14/2020 HST20-2324 10/15/2020 SS20-124012 10/19/2020 SD20-111276 3. An interview with the facility personnel on 10/22/2020 at 1000 hours in the laboratory revealed these dyes were the currently in use in the laboratory. She stated she was unaware they were expired. This confirmed the 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 procedure manual, manufacturer's instructions, temperature/humidity charts, corrective action logs, and patient records, the laboratory failed to ensure an effective QA (Quality Assessment) system was in place to monitor, assess, and correct problems identified in the laboratory. Findings 1. The laboratory failed to follow its own written policy ensure expired items were not available for use in patient testing during random review from September to October 2020. (refer D5417)