

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1021286	(X3) Date Survey Completed 10/14/2021
Name of Provider or Supplier Us Dermatology Partners Georgetown	Street Address, City, State 700 San Gabriel Village Blvd, Ste 105, Georgetown, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of manufacturer's instructions, temperature logs, patient logs, and interview, the laboratory failed to ensure the Mohs laboratory was within the operating specifications for the Leica CM1510S cryostat for three of three months reviewed. Findings follow. A. Review of the Leica CM1510S Instruction Manual on chapter 4. Setup under 4.1 Installation site requirements stated, "The place of installation must meet the following requirements: ... room temperature maximum 22 degrees Celsius" (72 degrees Fahrenheit). B. Review of the temperature logs from 3/30/21 - 9/07/21 showed the room temperature acceptable range was 41 - 95 degrees Fahrenheit. Review of the documented room temperature on the logs from 3/30/21 - 9/07/21 showed the room temperature was between 73 - 78 degrees every day of patient testing. C. Interview with the Mohs histotech on October 13, 2021 at 1600 hours in the Mohs laboratory confirmed the room temperature was above 72 degrees in the Mohs lab. D. Review of the patient logs showed 623 Mohs cases were performed in 2020, and approximately 550 cases were performed in 2021 to survey date. I. Based on surveyor observation, temperature logs, patient logs, interview and email, the laboratory failed to document the room temperature of the grossing laboratory for nine of 21 months reviewed. Findings follow. A. Surveyor observed 6</p>

bottles of Eprelia Hematoxylin 7211 reagent stored in the cabinet of the grossing laboratory showed a room temperature requirement of 15-30 degrees Celsius on the bottle. Surveyor observed 9 bottles of Leica Surgipath Hematoxylin 560 MX reagent stored in the cabinet of the grossing laboratory showed a room temperature requirement of 15 - 30 degrees Celsius on the bottle. B. Review of the temperature logs showed temperatures were recorded for 2020, but none were available for review for 2021. C. Interview with testing personnel #6 on October 13, 2021 at 1500 hours in the grossing laboratory acknowledged the laboratory stopped recording room temperatures at the end of 2020 because inspections at other sites had not asked for that. The Eprelia Hematoxylin reagent was used for the Hematoxylin and Eosin (H&E) stain for Mohs, and the Leica Hematoxylin was used in the grossing laboratory [to prepare H&E slides for dermatopathology review]. D. Review of the patient logs showed approximately 550 Mohs cases (with H&E staining) were performed to survey date in 2021. E. 6,237 cases have been processed for grossing and H&E staining to date in 2021 via email from the Office Manager on 10/14/2021.

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 review of reagent logs, laboratory policies and procedures, patient logs, and interview, the grossing laboratory failed to ensure the Carbol-Fuschin Solution used for the FITE Acid Fast-Stain was not available and in use beyond its expiration for three of 24 months reviewed. Findings follow. A. Review of the Carbol-Fuschin Lot Number Quality Control Log from 10/13/2019 - 10/13/2021 showed Lot 075563 expired on 05/01/2020 (in the Finish Date column on log), but Lot 084558 was not placed into use until 08/19/2020. B. Review of the FITE Acid Fast-Stain procedure, policy GTD-8.1, effective 09/01/2011, under Reagents included the Carbol-Fuschin Solution. Under Procedure stated, "the FITE stain is used for histologic visualization of acid-fast bacteria, Tubercle Bacilli, and Mycobacterium leprae (causative agent of leprosy) in tissue sections." C. Review of a query of the LIS from 05/02/2020 - 08/18/2020 showed two patient slides were prepared with the FITE Acid Fast-Stain: 1. GTW204631 on 07/20/2020, and 2. GTW47999 on 07/08/2020. D. Interview with testing personnel #6 listed on the CMS form 209, on October 13, 2021 at 1525 hours in the grossing laboratory confirmed testing was performed using the expired bottle, and explained the Finish Date on the log was when the last pour over from the original bottle occurred. KEY: LIS = Laboratory Information System