

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1014917	(X3) Date Survey Completed 08/20/2019
Name of Provider or Supplier Dermatology & Laser Center Of Oklahoma	Street Address, City, State 9306 S Toledo Court, Tulsa, OK	
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	The recertification survey was performed 08/20/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, office manager, and the histotechnician at the conclusion of the survey.
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: Based on a review of records and interview with the histotechnician, the laboratory failed to ensure the cryostat was maintained at an acceptable temperature. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor the laboratory performed microscopic interpretation of H&E (Hematoxylin and Eosin) slides from frozen sections from tissues obtained during Mohs surgeries and biopsies. The sections were cut using the Avantik QS11 and the Avantik QS12 cryostats; (2) The surveyor reviewed temperature records from 10/30/17 through 08/20/19. The defined acceptable cryostat temperature range, as stated on the monthly record, was -18 to -30 degrees C (Centigrade). The surveyor identified cryostat temperatures which were colder than the acceptable range. The findings follow: (a) Avantik QS11: The temperature was -31 degrees C on 3 of the 69 days of patient testing: (i) 12/18/17 (ii) 03/06/18 (iii) 12/04/18 (b) Avantik QS12: The temperature was -31 degrees C on 7 of the 164 days of patient testing: (i) 01/23/18 (ii) 02/05/18 (iii) 08/20/18 (iv) 12/13</p>

/18 (v) 02/33/19 (vi) 04/30/19 (vii) 07/25/19 (3) The surveyor reviewed the findings with the histotechnician who stated to the surveyor the laboratory failed to ensure the cryostat temperatures were acceptable, as listed above.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of records, written policy, manufacturer's instructions, and interview with the histotechnician, the laboratory failed to perform the manufacturer's required maintenance procedures. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor the laboratory performed microscopic interpretation of H&E (Hematoxylin and Eosin) slides of frozen sections from tissues obtained during Mohs surgeries and biopsies. The sections were cut using the Avantik QS11 and the Avantik QS12 cryostats; (2) The surveyor reviewed the manufacturer's maintenance instructions for the cryostats. The manufacturer required the following maintenance procedures be performed at "regular intervals" but did not define the frequency at which they were to be performed: (a) Avantik QS11: (i) Clean the cooling lamella (b) Avantik QS12: (i) Clean the cooling lamella (ii) Clean the touch screen (iii) Disinfect the blade carrier (3) The surveyor then reviewed the laboratory's written policy. The policy stated, "On the day of equipment use, proper functioning of the cryostat will be evaluated and recorded in the the 'Cryostat Routine Maintenance Record Log'." The policy did not define the frequency at which the cleaning and disinfecting procedures were to be performed on the cryostats; (4) The surveyor reviewed the maintenance records for the cryostats from 10/30/17 through 08/20/19. There was no documentation the maintenance procedures listed above had been performed on days of patient testing during the review period. The findings follow: (a) Avantik QS11: On 69 days of use: (i) October 2017 - On 1 of 1 day used: Day 31 (ii) November 2017 - On 2 of 2 days used: Days 6,27 (iii) December 2017 - On 3 of 3 days used: Days 12,18,19 (iv) January 2018 - On 4 of 4 days used: Days 4,5,8,9 (v) April 2018 - On 2 of 2 days used: Days 24,30 (vi) May 2018 - On 8 of 8 days used: Days 8,14,15,21,22,23,29,31 (vii) June 2018 - On 5 of 5 days used: Days 4,5,11,12,19 (viii) July 2018 - On 3 of 3 days used: Days 2,9,10 (ix) August 2018 - On 2 of 2 days used: Days 7,13 (x) September 2018 - On 2 of 2 days used: Days 20,24 (xi) October 2018 - On 1 of 1 day used: Day 22 (xii) January 2019 - On 4 of 4 days used: Days 4,7,22,29 (xiii) March 2019 - On 1 of 1 day used: Day 12 (xiv) April 2019 - On 1 of 1 day used: Day 2 (xv) May 2019 - On 7 of 7 days used: Days 7,13,14,20,21,28,30 (xvi) June 2019 - On 6 of 6 days used: Days 3,4,5,10,11,18 (xvii) July 2019 - On 11 of 11 days used: Days 8,9,10,12,15,16,18,23,25,29,30 (xviii) August 2019 - On 6 of 6 days used: Days 6,8,12,13,19,20 (b) Avantik QS12: On 164 days of use: (i) October 2017 - On 2 of 2 days used: Days 30,31 (ii) November 2017 - On 8 of 8 days used: Days 6,7,13,14,20,21,27,28 (iii) December 2017 - On 6 of 6 days used: Days 4,5,11,12,18,19 (iv) January 2018 - On 9 of 9 days used: Days 4,5,8,9,16,18,19,22,23 (v) February 2018 - On 7 of 7 days used: Days

5,6,12,13,19,27,28 (vi) March 2018 - On 8 of 8 days used: Days 2,5,6,12,13,16,26,27 (vii) April 2018 - On 10 of 10 days used: Days 2,3,9,10,16,17,20,23,24,30 (viii) May 2018 - On 11 of 11 days used: Days 1,7,8,14,15,21,22,23,24,29,31 (ix) June 2018 - On 8 of 8 days used: Days 4,5,11,12,18,19,25,26 (x) July 2018 - On 7 of 7 days used: Days 2,9,10,16,17,23,24 (xi) August 2018 - On 9 of 9 days used: Days 7,8,13,14,20,21,22,27,28 (xii) September 2018 - On 9 of 9 days used: Days 4,6,10,11,17,18,20,24,25 (xiii) October 2018 - On 9 of 9 days used: Days 1,2,15,16,22,23,29,30,31 (xiv) November 2018 - On 10 of 10 days used: Days 5,6,12,13,15,19,20,26,27,29 (xv) December 2018 - On 7 of 7 days used: Days 3,4,10,11,13,17,18 (xvi) January 2019 - On 12 of 12 days used: Days 3,4,7,8,14,15,17,22,24,28,29,30 (xvii) February 2019 - On 8 of 8 days used: Days 4,5,7,11,12,25,26,27 (xviii) March 2019 - On 8 of 8 days used: Days 4,5,7,11,12,25,26,29 (xix) April 2019 - On 11 of 11 days used: Days 1,2,8,9,15,16,22,23,24,29,30 (xx) May 2019 - On 4 of 4 days used: Days 6,7,21,28 (xxi) July 2019 - On 1 of 1 day used: Day 8 (5) The surveyor asked the histotechnician how often the cryostat maintenance listed above was performed. The histotechnician stated to the surveyor cleaning was performed daily and the cooling lamellas were cleaned as needed but performance of the maintenance procedures had not been documented; (6) The surveyor reviewed the findings with the histotechnician and explained the frequency at which the cleaning and disinfecting procedures were to be performed must be defined in the laboratory's written policy, and the performance of the maintenance procedures must be documented.

D5781

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the histotechnician, the laboratory failed to ensure corrective action was taken for unacceptable cryostat temperatures. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor the laboratory performed microscopic interpretation of H&E (Hematoxylin and Eosin) slides of frozen sections from tissues obtained during Mohs surgeries and biopsies. The sections were cut using the Avantik QS11 and the Avantik QS12 cryostats; (2) The surveyor reviewed temperature records from 10/30/17 through 08/20/19. The defined acceptable cryostat temperature range, as stated on the monthly record, was -18 to -30 degrees C (Centigrade). The surveyor identified cryostat temperatures which were colder than the acceptable range. The surveyor could not find documentation that corrective action (i.e. checking the temperature again at a later time, adjusting the temperature, etc.) had been taken for the unacceptable temperatures. The findings follow: (a) Avantik QS11: The temperature was -31 degrees C on 3 of the 69 days of patient testing: (i) 12/18/17 (ii) 03/06/18 (iii) 12/04/18 (b) Avantik QS12: The temperature was -31 degrees C on 7 of the 164 days of

patient testing: (i) 01/23/18 (ii) 02/05/18 (iii) 08/20/18 (iv) 12/13/18 (v) 02/33/19 (vi) 04/30/19 (vii) 07/25/19 (3) The surveyor reviewed the findings with the histotechnician and asked if corrective action had been taken for the unacceptable temperatures listed above. The histotechnician stated no corrective had been taken for the unacceptable cryostat temperatures.