

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0963936	<b>(X3) Date Survey Completed</b> 10/19/2020
<b>Name of Provider or Supplier</b> Lubbock Dermatology & Skin Cancer Ctr	<b>Street Address, City, State</b> 3601 22nd Street, Lubbock, 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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory's own Mohs procedure, Quality control logs and interview of facility personnel found the laboratory failed to follow their own procedure for preparing a quality control slide each day of patient testing in histopathology. The findings included: 1. Review of the laboratory's own procedure found on page 19 of the standard operating procedures notebook " A control slide will be made and evaluated each day that a frozen section is prepared." 2. Quality control records for frozen section slides were requested but not provided. 3. Interview of the histotechnician conducted on October 19, 2020 at 3:29 PM confirmed that the laboratory did not prepare a quality control slide each day that a frozen section of tissue specimen is tested.</p>
<b>D5413</b>	<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>

This STANDARD is not met as evidenced by:  
 Based on review of manufacturer's instructions, temperature charts, patient reports, and interview, the laboratory failed to ensure the temperature was maintained according to manufacturer's instructions for the Cryostat used for freezing and sectioning of tissue specimens for the laboratory's frozen histopathology specimens and Mohs specimens. A. Review of the Leica CM1510, CM1510 v1.OE-06/97, Cryostat Manual found at "6. Unpacking and Installation" under "6.2 Site requirements - Room Temperature always below 22 degrees Celsius (C)" (71.6 degrees Fahrenheit (F)). B. Random review of the laboratory's temperature charts from October 2019 - September 2020 showed the room temperature was exceeded on 31 of 63 days in October and November of 2019 and August 2020. October 2019: with temperature in degrees F 1. 9th: 74 2. 10th: 73 3. 11th: 73 4. 14th: 74 5. 15th: 73 6. 21st: 74 7. 22nd: 75 8. 23rd: 75 9. 25th: 73 10. 30th: 73 November 2019: with temperature in degrees F 11. 4th: 75 12. 5th: 73 13. 6th: 75 14. 7th: 73 15. 8th: 74 16. 11th: 75 17. 12th: 74 18. 13th: 73 19. 15th: 75 20. 19th: 73 21. 20th: 77 22. 21st: 73 23. 22nd: 73 24. 26th: 73 August 2020: with temperature in degrees F 25. 3rd: 75 26. 5th: 73 27. 10th: 74 28. 12th: 73 29. 14th: 73 30. 17th: 73 31. 26th: 73 C. Random review of patient reports showed the following patients were tested when temperatures exceeded the manufacturer's requirements for the Cryostat. 1. Review of randomly selected patient reports showed the following patient samples were processed for frozen histopathology: August 12, 2020: patient account #86661.0, specimen NFS20-879; August 14, 2020: patient account #57511.0, specimen NFS20-893 and patient account # 63927.0, specimen NFS20-500. 2. Review of randomly selected patient reports showed the following patient samples were processed for Mohs histopathology testing: August 10, 2020: patient account # 135654.0, specimen NS20-112. D. Interview with the histotechnician with the initials SM in the office verified the laboratory temperatures were outside the acceptable range.

**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 observation and interview, the laboratory failed to ensure reagents were not used when they have exceeded their expiration date. Findings follow. Surveyor observation on 10/19/2020 at 1400 hours in the laboratory showed 3 out of 8 unopened bottles of Cryptoseal 60, Lot 371531, had an expiration date of 05/2018. Interview with the histotechnician with the initials SM on 10/19/2020 at 1400 hours in the laboratory confirmed the bottles were expired and were used for cover slipping histopathology slides.

**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 quality control records, and interview of facility personnel, the laboratory failed to document the negative and positive reactivity of quality control slides for Hematoxylin and Eosin (H and E) staining on each day of patient testing between February 2019 and April 2020. The findings included: 1. Based on review of H and E stain quality control slide logs between February 2019 and April 2020 the laboratory documented acceptability of stain reactivity using "OK" in the column labeled results for each day of the month and the initials of the histotechnician responsible for staining slides, and the doctor's initials. 2. Interview of the histotechnician conducted on October 19, 2020 at 3:29 PM confirmed that physicians do not document quality or acceptability of staining on the Control Slide specimen logs.