

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2028520	(X3) Date Survey Completed 06/17/2022
Name of Provider or Supplier Arkansas Dermatology	Street Address, City, State 1075 Andrews Drive Conway, Conway, AR	
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: Through observation, review of laboratory records for cryostats utilized for performing Mohs dermatologic surgery, review of patient procedure logs, lack of documentation, and interview it was determined that the laboratory did not document that the cryostats used in the performance of Mohs surgery met the appropriate operating temperature requirements. Findings follow: A) During a tour of the laboratory on 6/17/22 at 09:23 am two cryostats used for frozen sections in Mohs surgery, serial numbers 89797 and 50995, were observed in the laboratory. B) In an interview on 6/17/22 at 09:25 am, the laboratory staff member, identified as number six on the CMS 209 form, stated that both cryostats were used for frozen sections during Mohs surgery. C) Review of temperature records for 2022 revealed that the appropriate operating temperature range for the cryostats was defined as minus 20 degrees to minus 30 degrees C. and the temperatures for cryostat 89797 was warmer than minus 20 degrees C. on 3/21/22 to 3/25/22 inclusive. D) Review of patient procedure logs revealed that five Mohs surgery procedures on patients, identified as numbers one through five on a separate patient identification list, were performed on 3/21/22. E) Upon request the laboratory could not provide documentation that cryostat 89797 was not utilized for the performance of Mohs surgery during the dates of 3/21/22 through 3/25/22 inclusive. F) In an interview on 6/17/22 at 10:55 am, the</p>

laboratory staff member, identified as number six on the CMS 209 form, stated that the laboratory could not document that cryostat 89797 was not used for the preparation of frozen sections performed for Mohs surgery on 3/21/22.

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:

Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow:
A) During a tour of the laboratory on 6/17/22 at 10:55 am five of twenty 95% one gallon reagent alcohol containers, lot# 087021 expiration date 2021-09-30 were observed in the laboratory flammable storage cabinet. B) In an interview on 6/17/22 at 10:55 am the laboratory staff member, identified as number 6 on the CMS 209 form, confirmed that the items, identified above, had exceeded their expiration dates and were available for use.