

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0962525	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Dermatology Center, PLLC	Street Address, City, State 7900 Dallas Street, Fort Smith, 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 review of the patient log book, patient reports, cryostat temperature log, lack of documentation, and interview it was determined that the laboratory failed to document the operating temperature of the cryostat in 19 of 700 Mohs surgery patients between 01/01/22 and 07/20/22. Findings follow: A) Review of cryostat temperature records revealed that cryostat temperatures were not documented on 2/21/22, 5/4/22, 7/6/22, 7/12/22, 7/13/22 and 7/20/22. B) Review of the patient log book and patient reports revealed that Mohs surgeries were performed on: * 2/21/22 (1 case patient identified as number one on a separate patient identification list) * 5/4/22 (3 cases patients identified as numbers two through four on a separate patient identification list) * 7/6/22 (4 cases patients identified as number five through eight on a separate patient identification list) * 7/12/22 (1 case patient identified as number nine on a separate patient identification list) * 7/13/22 (5 cases patients identified as number ten through fourteen on a separate patient identification list) * 7/20/22 (5 cases patients identified as number fifteen through nineteen on a separate patient identification list) C) Upon request the laboratory could not produce documentation of cryostat temperatures for 2/21/22, 5/4/22, 7/6/22, 7/12/22, 7/13/22 or 7/20/22. D) In an interview on 8/11/22 at 12:50 pm, the clinic personnel identified as number one and two on a separate personnel identification list confirmed that Mohs surgeries were</p>

performed on 2/21/22, 5/4/22, 7/6/22, 7/12/22, 7/13/22 and 7/20/22 and the cryostat temperatures were not documented on those dates.

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 it was determined that the laboratory failed to assure that supplies were not used when they have exceeded their expiration date. Findings follow: A) During a tour of the laboratory on 8/11/22 at 01:00 pm, three of three bottles of Potassium Hydroxide Solution (two bottles Lot # 1934524 with an expiration date of 12/12/21, and one bottles lot # K16841 with an expiration date of 2019-11 30) were observed in a supply cabinet and no unexpired Potassium Hydroxide was observed in the cabinet at that time . B) In an interview on 8/11/22 at approximately 01:10 pm, clinic staff members identified as numbers one and two on a separate staff identification list confirmed that the bottles were available for use, and had exceeded the expiration date.

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:

. Through a review of Mohs surgery logs, H&E stain quality control log, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to document staining quality for Hematoxylin and Eosin (HE) stain on each day of patient testing. As evidenced by: A) Review of the patient log book and patient reports revealed that Mohs surgeries were performed on: * 2/21/22 (1 case patient identified as number one on a separate patient identification list) * 5/4/22 (3 cases patients identified as numbers two though four on a separate patient identification list) * 7/6/22 (4 cases patients identified as number five through eight on a separate patient identification list) * 7/12/22 (1 case patient identified as number nine on a separate patient identification list) * 7/13/22 (5 cases patients identified as number ten through fouteen on a separate patient identification list) * 7/20/22 (5 cases patients identified as number fifteen through noneteen on a separate patient identification list) B) Review of the H&E stain quality control log revealed that no H&E stain quality control review was documented on 2/21/22, 5/4/22, 7/6/22, 7/12/22, 7/13/22, or 7/20/22 C) In an interview on 8/11/22 at 12:50 pm, the clinic personnel, identified as numbers one and two on a separate clinic personnel list, confirmed the laboratory did not document H&E stain quality on the days identified above and patients had Mohs surgery with the required H&E stained slides.