

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0467334	<b>(X3) Date Survey Completed</b>  02/08/2023
<b>Name of Provider or Supplier</b>  Little Rock Dermatology Clinic, Pa	<b>Street Address, City, State</b>  500 S University Ave, Suite 301, Little Rock, AR	
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>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> <p>This STANDARD is not met as evidenced by: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in one of two rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 2/8/23 at 8:30 a.m..two separate rooms (both histology laboratories) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that temperature records were presented for only one of the histology lab rooms (room number one). C) During a tour of the laboratory on 2/8/23 at 10:45 a.m. one container of Toluidine Blue ( lot # 66757 expiration date 2023-09) with a storage temperature requirement of 20 to 26 degrees C. and one container of Sigma-Aldrich natigen material (lot 140759 expiration date 2024-06-30) with a storage temperature requirement of 18 degrees C. to 25 degrees C were observed in the histology lab room number two. D) Upon request, the laboratory could not present the temperature records for the histology room (room number two) in which the supplies identified above were stored., E) In an interview on 2/8/23 at 11:03 a.m. the laboratory staff member (# 7 on the CMS 209 form) stated that the daily temperature of the histology room in which the supplies identified above were stored had not been monitored and recorded..</p>

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Through a review of personnel files for the seven testing personnel listed on the CMS-209 form as well as interviews with staff, it was determined the laboratory director failed to specify, in writing, the procedures each testing person can perform and whether supervision is required for one of the seven testing personnel. Survey findings follow: A) In an interview at 10:20 a.m. on 2/8/23, the laboratory staff member (number seven on the CMS 209 form) stated that she performs all tissue gross descriptions and the gross descriptions appear on the final report. B) Through a review of testing personnel employment files it was revealed that testing personnel (number seven on the CMS 209 form) lacked documented authorizations to perform tissue gross descriptions. C) In an interview on 2/8/23 at 10:20 a.m. the laboratory staff member (# seven on CMS 209 form) confirmed the laboratory director failed to give written authorization for her to perform tissue gross descriptions.