

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1034085	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Premier Dermatology Pllc	Street Address, City, State 901 Se Plaza Ave, Suite 5, Bentonville, 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 temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation in one of two rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 9/7/23 at 2:00 p.m. two separate rooms (main lab, storage room) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the storage room area. C) During a tour of the laboratory on 9/7/23 at 2:00 p.m. 3 boxes of Tissue Plus ACT with a storage temperature requirement of 4 degrees C. to 30 degrees C., lot # 4619 , expiration October 2026 and 3 boxes of Parapro LMP embedding media with a storage temperature requirement of 15 degrees C. , to 30 degrees C. , lot # 13195, expiration date 6/2028 were observed in storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored. E) In an interview on 9/6/23 at 2:15 p.m., the laboratory staff member (# 1 on the CMS 209) stated " no we don't have temperatures for the storage room".</p>
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 9/7/23 at 2:45 p.m, one of one bottles of Potassium Hydroxide Solution , lot # 0083 with an expiration date of 2022-03-23 was observed in a supply cabinet and no unexpired Potassium Hydroxide was observed in the cabinet at that time . B) In an interview on 9/7/23 at 2:45 p.m, clinic staff member (number 1 on the CMS 209 form) confirmed that the bottle was available for use, and had exceeded the expiration date.