

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0687904	(X3) Date Survey Completed 08/23/2024
Name of Provider or Supplier Ozark Dermatology Clinic	Street Address, City, State 4375 N Vantage Dr Ste 305, Fayetteville, 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: Observation, review of temperature records, lack of documentation and interview demonstrated 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 8/23/24 at 08:45 a.m., the surveyor observed two separate rooms (Histology Laboratory, Mohs Surgery Laboratory) containing laboratory items with a temperature storage requirement. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the Histology Laboratory. C) During a tour of the laboratory on 8/23/24 at 10:40 a.m. the surveyor observed 4 bottles of Harris Hematoxylin stain (lot # 2308335) expiration date 2025-03-30 with a storage temperature requirement of 15 degrees Centigrade (C.) to 30 degrees C., and 1 bottle of CAT Hematoxylin Stain (lot # 32924 A) expiration date 2025-09-30 with a storage temperature requirement of 20 degrees Centigrade (C.) to 25 degrees C., in the Histology laboratory.. D) Upon request, the laboratory could not present the temperature records for the Histology Laboratory room in which the supplies identified above were stored. E) In an interview on 8/23/24 at 10:57 a.m., the laboratory staff member (# 3 on form CMS 209) confirmed that temperature records for the Histology Laboratory were not kept.</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:

Review of personnel records of five testing personnel performing highly complex laboratory procedures (tissue gross descriptions), lack of documentation and interviews with laboratory staff, determined the laboratory director failed to give written authorization for one of five testing personnel reviewed to perform highly complex procedures without direct supervision. Survey findings follow: A) A review of personnel records of five testing personnel, who perform highly complex procedures, revealed that one (#13 as listed on the form CMS-209) failed to have the laboratory director's written authorization to perform highly complex procedures without supervision. B) Upon request, the laboratory was unable to provide documentation of the authorization to perform highly complex procedures for the personnel identified above. C) In an interview, at 10:57 a.m. on 8/23/24, laboratory staff member (#3 as listed on form CMS 209) confirmed the lack of written authorizations for the personnel identified above and that they performed highly complex procedures.