Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1013059	07/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatologist Medical Group Of North County Inc	1200 Garden View Rd, Ste 108, Encinitas, CA	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the surveyor's review of fifteen (15) randomly selected patient records for KOH, scabies, and dermatopathology and interviews with the office manager (OM), charge nurse (CN), and licensed vocational nurse (LVN) on July 23, 2024, at approximately 3:00 p. m., the laboratory failed to correctly match the date of visit in the patient's chart against the preventive maintenance (PM) log sheet and slide label. The findings included: 1. The surveyor reviewed a total of 15 randomly selected patient records that consisted of ten dermatopathology, three KOH, and two scabies records from January 11, 2022, to April 17, 2024. One out of 15 records did not match for the date of service from the patient's chart against the PM log and slides presented at the time of the survey. 2. It was the practice of the laboratory that the labeling of slides only consisted of the date of visit, the patient's name, and the source of the specimen. No case or accession number is used in the current system. 3. Upon further review of other slides of the same date of visit, it was determined that all patient slides for June 20, 2022, were labeled under June 19, 2022. 4. The OM, CN, and LVN affirmed on July 23, 2024, at approximately 3:00 p.m., that all information stated on statements #1, #2., and #3 are correct. 5. Based on the laboratory testing declaration submitted on the day of survey, the laboratory performed 4,838 tests for KOH, scabies, and dermatopathology annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures and interviews with the office manager (OM), charge nurse (CN), and licensed vocational nurse (LVN), it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings included: 1. Based on the survey on July 23, 2024, at approximately 2:30 p.m., no documentation could be retrieved to show that the laboratory was performing quality assessment and assurance. 2. The OM, CN, and LVN affirmed on July 23, 2024, at approximately 2:30 p.m., that the laboratory did not have any documentation that followed the written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration submitted on July 23, 2024, signed and dated by the laboratory director, the laboratory performed 4,838 tests for KOH, scabies, and dermatopathology annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the interviews with the office manager, charge nurse, and licensed vocational nurse, review of the laboratory's policies and procedures, observations during the tour of the facility, and review of fifteen randomly chosen patient records on July 23, 2024, the laboratory director is herein cited for failure to ensure that several aspects of the analytic and postanalytic phases of the laboratory testing were monitored. Findings included: 1. Identification and integrity of patient records, logs, and slides. See D5203. 2. No quality assessment documentation found. See D5391.