Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0560613	**(X3) Date Survey Completed** 04/17/2025
Name of Provider or Supplier Robert Hartman Md	**Street Address, City, State** 5400 Balboa Blvd, Ste 329, Encino, 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**
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure binder, observations during the tour, and an interview with the administration manger (AM), it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory lacked an established safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed. 2. The laboratory did not have an eye wash station or a portable eye wash bottle in place, as observed and noted by the surveyor during the facility tour. 3. The AM affirmed by interview on April 17, 2025 at approximately 3:50 p.m., that the laboratory lacked a safety policy and procedure, as well as an eye wash in the laboratory area. 4. The safety of laboratory personnel could not be assured. 5. The annual testing declaration form (Lab-144) signed by the director on April 14, 2025, stated that the laboratory processed approximately 1,214 patient tests for Mycology, Parasitology, and Dermatopathology during the time when neither a safety protocol nor an eye wash station/bottle was in place.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, peer review records, five (5) randomly selected patient records, and an interview with the administration manager (AM); it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the years 2022, 2023, and 2024. The findings include: 1. The laboratory's policies and procedures for proficiency testing stated that cases are sent to another facility to verify the accuracy of results for Dermatopathology. However, no records for the years 2022, 2023, and 2024 were found to have met the 493.1236(c) standard regulation. Therefore, the accuracy of patient results could not be assured. 2. Review of the laboratory's proficiency testing protocol for Mycology and Parasitology indicated that the laboratory director (LD) will attend the assessment class at San Fernando Valley Dermatological Society. However, no documentation found for the years 2022, 2023, and 2024. 3. The AM affirmed by interview on April 17, 2025, at approximately 2:35 p.m., that the laboratory missed to perform proficiency testing as mentioned in statements #1 and #2. 4. The laboratory's testing declaration form submitted at the time of the survey stated that 1,214 tests in Mycology, Parasitology, and Dermatopathology are performed annually during the time that no proficiency testing that met the CLIA requirements were performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) 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 surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, observations during the tour of the facility, and an interview with the administration manager (AM) on April 17, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Lack of safety procedures and measures. See D3011. 2. Lack of proficiency testing for the years 2022, 2023, and 2024. See D5217.