Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0563935	**(X3) Date Survey Completed** 10/08/2021
Name of Provider or Supplier Laurie M Woll Do Dermatology	**Street Address, City, State** 9301 Central Ave Ste 201, Montclair, 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**
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: Based on the surveyors' observation, examination of laboratory reagents, and interview with the office manager (OM), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, October 8, 2021 at approximately 11:10 a.m. the surveyor found the KOH reagent used for microscopic examination for the prescence of yeast and fungal elements Lot number 9711-00 being used beyond its expiration date (5/31/2021). 2. The OM affirmed on 10/08//2021 at approximately 11: 45 a.m. testing personnel using the KOH reagent beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 30 KOH mycology samples annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on surveyor's observation, lack of maintenance documentation, and interview with the office manager (OM)); it was determined that the laboratory failed to follow a maintenance protocol for the Fisher Scientific Micromaster microscope that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. Based on the surveyor's observation and documents review on October 8, 2021 at approximately 11:00 a.m. there was no evidence or records found on the microscope maintenance or calibration for the years 2020 and 2021. 2. The OM confirmed on an interview on 10/8/2021 at approximately 11:15 a.m. that the laboratory failed to follow a maintenance protocol for the Fisher Scientific Micromaster microscope used for mycology, parasitology, and histopathology examinations. 3. Based on the laboratory's yearly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 1,970 samples.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, lack of preventive maintenance records, use of a expired reagent, randomly chosen patients, and interview with the office manager; it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance. See D5417 and D5433.