Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0904002	12/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Specialists, Inc	25495 Medical Center Dr Ste 200, Murrieta, 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 observation of the KOH reagent bottles from two locations in the laboratory's office areas, where the health providers performed Provider Performed Microscopy (PPM) testing procedures, and interview with the office manager, it was determined that the laboratory failed to stop using exceeded the expiration date of 10% KOH reagents, and failed to ensure the strength or stability of the reagents. The findings included: a. The laboratory is a dermatology laboratory, which was certified for 120 mycology and 130 parasitology, moderate complexity testing and subspecialties of microbiology, and 610 histopathology, a high complexity testing. b. At the time of the survey, 12/10/20 @ 10:30 am, there were two 10% KOH regent bottles present in two different areas where a microscope stands each area. c. The 10% KOH was labelled with MCC (Medical Chemical Corporation) and both bottles expired in August 2019. d. The health providers used 10% KOH expired in August 2019 for their KOH testing in 2020. e. The laboratory performed KOH in approximately 20 (last survey estimated) patient specimens 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 observation of the laboratory performed microscopic examination areas, and interview of with the office manager, it was determined that the laboratory failed to follow and document the maintenance activities or protocols established by the laboratory, or failed to follow the manufacture's instruction to perform and document the preventive maintained activities. The findings included: a. The laboratory is a dermatology laboratory, was certified for 120 mycology and 130 parasitology (moderate complexity testing and subspecialties of microbiology), and 610 histopathology, a high complexity testing to examine skin tissues. b. The laboratory performed KOH and histopathological examinations in Mohs procedures, all require microscope to examine. c. At the time of the survey, 12/10/20 @ 10:40 am, observed two microscopes, one Nikon with number 029440, and the other, Olympus CX31 RBSF in different locations. d. There was not any record or tag on the body of the Nikon microscope to indicate that ever maintained or serviced according the laboratory established policies and procedures or following the manufacturer's instructions. e. The other Olympus microscope had a tag identified "Oct. 2018" on the body of the microscope. f. The office Manager later, presented maintenance records from Lab Equipment Service & Supplies LLC San Marcos, CA dated 11-2-17 and in the records identified "Next PM Due Oct 2018". g. The laboratory failed to follow maintenance protocols and document the maintenance activities that ensure equipment, the microscopes, for accurate and reliable test results.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) 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 observation of the laboratory facility, equipment and microscope working areas, review lack of the equipment maintenance records, and interview with the office Manager, it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory, and failed to ensure the establishment and maintenance of acceptable levels of analytical performance for microscopic examination of KOH wet mount and histopathological testing. The findings included: a. The laboratory is a dermatology laboratory, which was certified for 120 mycology and 130 parasitology, moderate complexity testing, and 610 histopathology, a high complexity testing, a microscope is essential for their examination. b. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for KOH and histopathology test systems. c. The laboratory performed KOH wet mount for scabies, and histopathological exam in Mohs procedures. d. The laboratory used an expired 10% KOH reagent in wet mount examinations, see D-5417. e. The laboratory failed to

	follow its equipment maintain protocols for the microscopes maintenance to ensure microscopic exams are accurate and reliable for the test results. see D-5433