Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0857935	(X3) Date Survey Completed 09/14/2022
Name of Provider or Supplier Preferred Dermatology	**Street Address, City, State** 7937 S Painter Ave, Whittier, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of documentation, review of testing personnel competency assessment records, and interview with the technical consultant (TC) and testing personnel (TP) on September 14, 2022, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the TC and TP competency for the years 2021 and 2022. Findings include: 1. Based on review of the laboratory's policies and procedure and competency evaluations' records the laboratory failed to establish and follow written policies and procedures for competency assessment of the TC and TP. 3. The laboratory fail to provide documentation of training or competency assessment for the TC and TP performing Mohs surgery sample processing and staining at the laboratory for the year 2020 and 2021. 4. This deficient practice was affirmed by interview with the TC and TP on September 14, 2022, at approximately 1:15 p.m.
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 lack of the laboratory's policies & procedures, review of five (5)

	randomly chosen patients' Mohs reports, four (4) Histopathology slides, quality control records, peer review records, and interviews with the laboratory's technical consultant (TC) on September 14, 2022; it was determined that the laboratory failed to verify, at least twice annually, the accuracy of its Mohs and Histopathology tests for the year 2021for one Mohs and Histopathology testing diagnosing physician. The findings included: 1. The laboratory did not have any documentation showing that it had verified its Mohs and Histopathology tests' accuracy for the year 2021 for one Mohs surgeon and dermatopathologist performing slide reading and providing patients' diagnosis. Therefore, the accuracy of the laboratory's test results for patients for Mohs and Histopathology procedures, cannot be assured. 2. The LD and TC confirmed at approximately 1:00 p.m., that the laboratory did not have any record to verify its Mohs and Histopathology test accuracy for the year 2021. 3. The laboratory's testing declaration form signed by the laboratory director, stated that the laboratory performs 923 Histopathology and Mohs tests annually.
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 technical consultant (TC); 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, September 14, 2022, at approximately 11:30 a. m. the surveyor found no KOH reagent used for microscopic examination for the presence of yeast and fungal elements and an expired Chlorazol Black E reagent Lot # 8094 expiration date 4/14/2020. 2. The TC affirmed on 9/14/2022 at approximately 11: 35 a.m. testing personnel did not find the KOH reagent and Chlorazol Black E reagent was used beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 52 KOH mycology samples 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 review of the laboratory's records for policies and procedures, no KOH reagent available, use of expired reagents in Mycology, lack peer review for 2021, lack Mohs technician training and technical supervisor (TC) competency records, and interview with the laboratory director and TC on September 14, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D5209, D5217, and D5417.