Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2024886	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Dermatology Center Of Pasadena	625 S Fair Oaks Ave Ste 200, Pasadena, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on the lack of policies and procedures manual for documentation, reports in mycology, parasitology, Mohs slides, and histopathology retention, review of ten (10) randomly chosen dermatopathology test records, and interview with the medical assistant (MA); the laboratory failed to have a policy for mycology, parasitology, Mohs slides, and histopathology document and slide retention. The findings included: 1. On the day of survey, January 31, 2024, at approximately 12:00 p.m. no retention of documents and records was found. 2. The MA confirmed by interview on January 31, 2024, at approximately 12:00 p.m. that the laboratory did not have a policy for documents retention for mycology, parasitology, Mohs slides, and histopathology. 3. The laboratory reports performing approximately 700 mycology, parasitology, and histopathology patients' tests results 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 review of ten (10) randomly chosen patient samples, review of test requisitions, final reports, quality control documents, preventive maintenance, quality assurance, and interview with the laboratory's medical assistant (MA); it was determined that the laboratory failed to establish and follow written quality assurance policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. The findings included: 1. On the day of the survey 1/31/2024 at approximately 11:45 a.m. no documentation could be retrieved to show that the laboratory had written policies and procedures for quality control failures, preventive maintenance, and quality assessment and assurance. This correction process involves policies for quality assessment and assurance, and policies for preventing problems that have been identified. 2. The MA confirmed on 1/31/2024 at approximately 12:00 p.m. that the laboratory did not have written quality assurance plan that reflect the current practice for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. 3. The testing declaration submitted and signed by the laboratory director (LD) on 1/31/2024 during the survey estimated 700 tests performed annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures and interview with the medical assistant (MA), it was determined that the laboratory failed to have available and follow written procedures for mycology, parasitology, and histopathology. The findings included: 1. On the day of the survey on January 31, 2024, at approximately 11:30 a.m., the laboratory failed to provide written policies and procedures for mycology, parasitology, and histopathology test procedures performed in the laboratory. 2. For ten (10) out of ten (10) randomly selected patient test results for mycology, parasitology, and histopathology reviewed covering period from 12/08 /2021 to 10/24/2023, all the patients had mycology, parasitology and histopathology test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The MA confirmed on 01/31/2024 at approximately 11: 30 a.m. that the laboratory did not have written policies and procedures available for mycology, parasitology, and histopathology tests performed in the laboratory.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour and interview with the medical assistant (MA), the laboratory failed to label reagents, stains, and dyes used for Mohs sample processing. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on January 31, 2024, at approximately 1:30 pm.; no opening, preparation, or expiration date labels were used or documented for the reagents, stains, and dyes used on Mohs sample processed daily. 2. The MA affirmed in an interview conducted 1/31/2024, at approximately 1:30 p.m. that the reagents mentioned in statement 1 were not labeled with the opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 600 histopathology test samples including Mohs.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of five (5) Mohs surgery records an interview with the medical assistant (MA), one (1) out of five (5) Mohs patient reviews was discrepant in their findings and report. The findings included: 1. The survey team reviewed five (5) Mohs patient records. One (1) out of five (5) records was discrepant: in the slide, mapping records stage III was determined as the final stage. However, the final report indicated stage IV as the final stage. 2. During an interview with the survey team, the MA affirmed that the discrepancy in number 1 above was recorded erroneously. Further investigation is needed to be performed. No corrective action was available at the time of the survey. 3. The laboratory reported approximately 600 Mohs cases performed 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 surveyor's review of the laboratory's records, policies and procedures, patients' test results records, quality assessment documentation, and interviews with the laboratory's medical assistant (MA) on January 31, 2024; it was determined that

	the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3043, D5291, D5401. D5415, and D5821.