Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2061255	08/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Couture Dermatology And Plastic Surgery	9950 W Flamingo Road, Ste 105, Las Vegas, NV	

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
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 7, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a random audit of three Mohs patients between the dates of June 9, 2023 and March 18, 2024, the absence of a specimen identification policy and procedure, and an interview with the lead medical assistant revealed that the laboratory failed to ensure that positive identification of patient specimens was maintained from the time of collection through completion of testing and reporting of results. Findings include: 1. A random patient audit of three Mohs patients tested between the dates of June 9, 2023 and March 18, 2024 revealed that the laboratory failed to include the patient medical record number as a second unique identifier on the Mohs log and Mohs slides. 2. There was not a director approved policy and procedure specifying what unique patient identifers were to be used on the Mohs log and Mohs slides to ensure positive identification of patient specimens from collection through the reporting of results. 3. The lead medical assistant stated that the second unique identifier to be used was the patient medical record number, and confirmed the findings during an interview conducted on August 7, 2024 at approximately 11:30 AM. This is a repeat

	deficiency that was previously cited on the CLIA recertification survey conducted on May 25, 2022. The laboratory performs approximately 400 Histopathology procedures annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A review of the laboratory temperature logs, and an interview with the lead medical assistant revealed that the laboratory failed to ensure that the refrigerator temperatures used for the storage of the Dermatophyte Test Medium (DTM) was documented each day that the laboratory was open. Findings include: 1. A review of the laboratory temperature logs revealed that the laboratory failed to ensure that the refrigerator temperatures used for the storage of the Dermatophyte Test Medium (DTM) was documented on 20 of 22 days during the month of December, 2022. 2. The finding was confirmed during an interview with the lead medical assistant on August 7, 2024 at approximately 11:30 AM. The laboratory performs approximately 140 Mycology tests annually.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the quality control records for the Dermatophyte Test Medium (DTM) and an interview with the lead medical assistant, the laboratory failed to ensure that the documentation of the quality controls included the lot number and expiration date of the media to confirm which lot numbers were deemed acceptable for use in patient testing. Findings include: 1. A review of the quality control log sheet for the DTM testing between the dates of February 10, 2020 and March 25, 2024 revealed that there was no documentation of the lot number and expiration dates for the test media tested to determine which lot numbers were acceptable for patient use. 2. The findings were confirmed during an interview conducted with the lead medical assistant on August 7, 2024 at approximately 10:45 AM. The laboratory performs approximately 140 mycology tests annually.

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of July 5, 2022 and March 18, 2024, a review of the laboratory refrigerator temperature logs, a review of the Dermatophyte Test Medium (DTM) quality control log, a review of the a completed laboratory Quality Assessment Review Form, a review of the laboratory Quality Assessment Plan, and an interview with the lead medical assistant and the office manager, the director failed to ensure that the established quality assessment program was maintained to assure the quality of laboratory services and to identify failures in quality as they occur. Findings include: 1. A random patient audit between the dates of July 5, 2022 and March 18, 2024 revealed that the director failed to ensure that the laboratory failed to include a second unique identifier on the Mohs log and the Mohs slides. An interview with the lead medical assistant on August 7, 2024 at approximately 11:30 AM revealed that the patient medical record number was to be used as a second identifier for patient specimens. (Refer to Tag D5203) 2. A review of the laboratory temperature logs revealed that the laboratory failed to ensure that the refrigerator temperatures used for the storage of the Dermatophyte Test Medium (DTM) was documented on 20 of 22 days during the month of December, 2022. (Refer to Tag D5413) 3. A review of the quality control log sheet for the DTM testing between the dates of February 10, 2020 and March 25, 2024 revealed that there was no documentation of the lot number and expiration dates for the media tested to determine which lot numbers were acceptable for patient use. (Refer to Tag D5477) 4. A review of the Quality Assessment Review Form completed on November 9, 2023 revealed that the quality assessment plan was not effective to detect and correct errors in specimen identification, maintenance of refrigerator conditions for the storage of DTM, and the completeness of quality control documentation for the DTM. The office manager stated that there were no supporting documents for the items that the completed form indicated had been reviewed and/or corrected during an interview conducted on August 7, 2024 at approximately 12:00 PM. The laboratory performs approximately 140 Mycology tests and 400 Histopathology tests annually.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on an absence of initial training and competency assessment records, and an interview with the lead medical assistant, the director failed to ensure that there was documentation of initial training and competency assesment for the physician assistants reading Dermatophyte Test Medium (DTM) testing were trained and

	deemed competent prior to performing patient testing. Findings include: 1. There was no documentation of initial training and competency assessment for two of two physician assistants reading Dermatophyte Test Medium (DTM) tests prior to performance of patient testing. 2. The finding was confirmed during an interview with the lead medical assistant conducted on August 7, 2024 at approximately 11:00 AM. The laboratory performs approximately 140 mycology tests annually.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on an absence of initial training and competency assessment records, and an interview with the lead medical assistant, the Technical Supervisor failed to ensure that there was documentation of training and competency assesment for the physician assistants reading Dermatophyte Test Medium (DTM) testing were trained and deemed competent semi-annually during the first year of patient testing. Findings include: 1. There was no documentation of semi-annual training and competency assessment for two of two physician assistants reading Dermatophyte Test Medium (DTM) tests during the first year of patient testing. 2. The finding was confirmed during an interview with the lead medical assistant conducted on August 7, 2024 at approximately 11:00 AM. The laboratory performs approximately 140 mycology tests annually.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on an absence of initial training and competency assessment records, and an interview with the lead medical assistant, the tecnical supervisor failed to ensure that there was documentation of training and competency assesment for the physician assistants reading Dermatophyte Test Medium (DTM) testing were trained and deemed competent annually after the first year of patient testing. Findings include: 1. There was no documentation of annual training and competency assessment for two of two physician assistants reading Dermatophyte Test Medium (DTM) tests after the first year of patient testing. 2. The finding was confirmed during an interview with the lead medical assistant conducted on August 7, 2024 at approximately 11:00 AM. The laboratory performs approximately 140 mycology tests annually.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)

	Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on a random patient audit of patients tested for dermatophytes using Dermatophyte Test Medium (DTM) between the dates of July 5, 2022 and December 30, 2022, a review of State of Nevada Division of Public and Behavioral Health records, and an interview with the lead medical assistant, the laboratory failed to ensure that the physician assistants performing the DTM testing obtained certification as Office Laboratory Assistants, as required by the State of Nevada. Findings include: 1. A random patient audit of patients tested for dermatophytes using Dermatophyte Test Medium (DTM) between the dates of July 5, 2022 and December 30, 2022 revealed that two of three patients results were each read and reported by two physician assistants. 2. A review of the State of Nevada Division of Public and Behavioral Health Records revealed that the two physician assistants did not possess certification as Office Laboratory Assistants as required by the State of Nevada. 3. The findings were confirmed during an interview with the lead medical assistant conducted on August 7, 2024 at approximately 11:30 AM. The laboratory performs approximately 140 mycology tests annually.