Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2161197	08/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Signature Plastic Surgery And Dermatology	6930 S Cimarron Ste 100, 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 initial CLIA certification survey conducted at your facility of August 31, 2021. 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 patient audit of three patients tested between the dates of January 15, 2021 and March 26, 2021, a review of the director approved policy and procedure entitled "Slide Labeling," the director approved policy entitled, "Internal Quarterly Quality Assessment," and an interview with the office manager, and the medical assistant, the laboratory failed to ensure that the established policies and procedures were followed to maintain the positive identification and consistent documentation of the patient information for the specimen from the time of collection of the specimen through the reporting of the test results. Findings include: 1. A random patient audit between the dates of January 15, 2021 and March 26, 2021 revealed that there was no unique patient identification number that corresponded to the patient biopsy reports recorded on the Mohs log, and that the specimen identification information was not consistent through the pre-analytical, analytical and post-analytical phases of testing for three of three patient records reviewed. 2. A review of the patient record identified on the Mohs log as case number 0002, performed on January 15, 2021, revealed that

	the Mohs case number was not written on the patient slide labels, and no identification number that corresponded to the biopsy case number, S20-008068, was included on the Mohs log. The Mohs slide labels included the patient name, the date of service, the stage of the procedure, designated with the Roman numerals I and II, and the site of the Mohs procedure. One of two slide labels included a number designated as ACNC# S21-000098. The second of two slide labels included the letters ACNC#, but no number was written on the slide. The reference biopsy number written on the Mohs map, S21-000098, did not match the biopsy case number of S20-008068. 3. A review of the patient record identified on the Mohs log as case number 0007, performed on February 12, 2021, revealed that the biopsy case number, PH21-000007, was not included on the Mohs log. The biopsy case number was included on the Mohs map and the slide labels. 4. A review of the patient record identified on the Mohs log as case number 0012, performed on March 26, 2021, revealed that the Mohs case number on the log was not consistent in the final Mohs operative report, and that the Mohs log did not include the biopsy case number, PH21-000146, which was written on the Mohs map, and written on the Mohs slide labels. On the Mohs final operative report, the Mohs case number was identified as 0013. 5. The director approved policy entitled, "Internal Quarterly Quality Assessment Audit," in the section entitled, "Analytic" stated, "Slides unique ID correspond to Pathology report." 6. The director approved policy entitled, "Slide Labeling" stated in step 2, "Slides are to be labeled with: Mohs Log Accession Number, Patient Name, Number of Stages (will be marked with Roman Numeral; stage I, II, III, etc.), Quadrant or number of tissue/chunks per stage will be marked with numeral; # "1", "2", "3", etc., Number of slides per case will be marked level "A", for first cuts, level 'B' for second, and so on." 7. The findings were confirmed during an interview with the office manger and the medical assistant conducted on August 31, 2021 at approximately 12:30 PM. The laboratory performs approximately 50 histopathology 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 review of the director approved policy entitled, "Internal Quarterly Quality Assessment Audit," a review of the completed Quarterly Patient Quality Assurance Checklists for the dates of January 15, 2021 and March 26, 2021, a review of the completed "Quarterly Quality Assurance Checklist," and an interview with the office manager and medical assistant, the director failed to ensure that the established policy and procedure was consistent with the procedures used in the laboratory, and that the quality assessment activities were adequate to detect and correct discrepancies in the specimen identity in the pre-analytic, analytic, and post-analytic phases of Mohs testing. Findings include: 1. A review of the completed Quarterly Patient Quality Assurance Checklist for the dates of January 15, 2021 and March 26, 2021 revealed that the quality assurance review failed to detect and document corrective action for the discrepancies between the accession numbers written on the completed checklists and the Mohs case numbers written on the Mohs log. The Quarterly Patient Quality Assurance Checklist for January 15, 2021 recorded the accession number for the patient case reviewed as S20-007844. The Mohs log recorded the accession number as 0003. The Quarterly Patient Quality Assurance Checklist for March 26, 2021 recorded

	the accession number for the patient case reviewed as PH21-000052. The Mohs log recorded the accession number as 0010. 2. The director approved policy entitled, "Internal Quarterly Quality Assessment Audit" instructions did not correspond to the information reviewed on the Quarterly Patient Quality Assurance Checklist for the pre-analytic phase of testing. The policy stated, "Complete the Quarterly Quality Assessment Checklist by confirming the following for each case:". In the section entitled 'Pre-Analytic" the instructions stated, "Requisition unique name and DOB correspond to LIS Accessioned name and DOB," and "Requisition specimen source and LIS specimen source correspond." On the completed Quarterly Patient Quality Assurance Checklists, in the section entitled "Pre-Analytical," the items checked off as reviewed were designated as: "Specimens were logged in correctly." The sub sections were designated as, "Lab requisitions and maps contain correct information", "Specimens were handled and collected according to protocol," and "Specimens were labeled legible prior to receipt in the laboratory." 3. The director approved policy entitled, "Internal Quarterly Quality Assessment Audit" instructions did not correspond to the information reviewed on the Quarterly Patient Quality Assurance Checklist for the analytic phase of testing. The policy stated, "Complete the Quarterly Quality Assessment Checklist by confirming the following for each case:". In the section entitled "Analytic" the instructions stated, "Slides unique ID correspond to Pathology Report", Gross description and cassette summary correspond to specimens submitted", "Microscope maintenance is current", "Provider verification of accuracy." On the Quarterly Patient Quality Assurance Checklist, in the section entitled "Analytic" the items checked as reviewed were designated as "Specimen was logged and accession number given", "Dye markings were handled properly", "Proper embedding was followed correctly", "Cryostat sectioning was done properly", "Any necessary remedial action was performed and documented", "Quality control stain results were examined for possible problems." The laboratory does not perform gross analysis of specimens, and the laboratory does not embed tissues. 4. The director approved policy entitled, "Internal Quarterly Quality Assessment Audit" instructions did not correspond to the information reviewed on the Quarterly Patient Quality Assurance Checklist for the post-analytic phase of testing. The policy stated, "Complete the Quarterly Quality Assessment Checklist by confirming the following for each case:". In the section entitled "Post-Analytic," the policy stated "Final pathology report patient information corresponds to requisition," and "Final report includes address and CLIA ID of technical lab and sign out location." On the Quarterly Patient Quality Assurance Checklist, in the section entitled "Post-Analytical" the items checked as reviewed were designated as "Slides were reviewed by surgeon", and "Map and slides were properly reported by surgeon." 5. The director approved policy entitled, "Internal Quarterly Quality Assessment Audit" instructions did not correspond to the information reviewed on a separate quality assurance checklist, entitled "Quarterly Quality Assurance Checklist" that was completed. The "Quarterly Quality Assurance Checklist" included designations to review "Patient Test Management," "Quality Control Policies," "Laboratory Safety Policies," "Proficiency Testing Policies," "Personnel Policies," and "Quality Assurance Program." 6. The Quarterly Patient Quality Assurance Checklists that were completed for two patients that were tested on January 15, 2021 and on March 26, 2021, and the Quarterly Quality Assurance Checklists were not dated to indicate the date that the quality assessment was performed. The checklists were not signed by the person who completed them. The checklists were not signed by the laboratory director. The laboratory performs approximately 50 histopathology tests annually.