Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2001285	01/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Phoenix Skin Medical Surgical Group	5056 N Central Avenue, Phoenix, AZ	

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
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 review of the patients' Mohs map, review of patient slides, review of the electronic test report, review of the laboratory's Mohs log and interview with the laboratory director, the laboratory failed to follow established procedures to ensure positive identification of patient's dermatopathology specimens throughout the test reporting process. Findings include: 1. The laboratory began patient testing under the sub-specialty of Histopathology on September 10, 2020, with an approximate annual test volume of 900. The laboratory performs the microscopic interpretation for Mohs specimens and frozen biopsies. 2. It is the practice of the laboratory to assign a unique case number to each patient's Mohs specimen. The unique case number is included on the laboratory's Mohs log, the patient's Mohs map, the patient slide(s) and the patient's electronic test report. 3. Review of the Mohs map for patient J.V. from testing performed on 4/07/2022 indicated the Mohs case number as "M22-184" (for Stage II). The Mohs log, Mohs slides and Mohs Operative Report for this patient indicated the Mohs case number as "M22-185". 4. The laboratory director interviewed during the survey on 1/19/2023 at 12:10pm confirmed that the Mohs map indicated above listed the incorrect case number for Stage II. The laboratory director acknowledged that the unique case number for this patient, tested on 4/07/2022 was M22-185.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f)

	(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the laboratory director, the laboratory failed to have two pathology reports signed by the individual who performed the examination and made the diagnosis. Findings include: 1. The laboratory began patient testing under the sub-specialty of Histopathology on September 10, 2020, with an approximate annual test volume of 900. The laboratory performs the microscopic interpretation for Mohs specimens and frozen biopsies. 2. One out of one frozen biopsy test reports reviewed during the survey for patient FBX21-02 from 01/26/2021 failed to include the signature of the individual making the diagnosis. 3. One out of three Mohs test reports reviewed during the survey for patient M22-551 from 12/06/2022 failed to include the signature of the individual making the diagnosis. 4. The laboratory director interviewed during the survey on 1/19 /2023 at 12:25pm confirmed that the pathology reports indicated above were not signed by the individual who performed the examination and made the diagnosis.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test records and patient slides associated with Frozen Biopsy testing and interview with the laboratory director, the laboratory failed to indicate the correct testing date on the patient's slide. Findings include: 1. The laboratory began patient testing under the sub-specialty of Histopathology on September 10, 2020, with an approximate annual test volume of 900. The laboratory performs the microscopic interpretation for Mohs specimens and frozen biopsies. It is the practice of the laboratory to label the patient slide for frozen biopsy testing with the date, patient name and unique case number. 2. Review of the frozen biopsy slide for case# FBX21-02, indicated the date as 1/26/2020 . The pathology report date indicated the testing was performed on 1/26/2021, not 01/26/2020. 3. The laboratory director interviewed on 1/19/2023 at 12:40pm confirmed that the frozen biopsy slide indicated above was labeled with the incorrect testing date.