Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2181402	09/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Phoenix Surgical Dermatology Group, Llc	4550 E Bell Rd Ste 150, 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 a frozen biopsy test report issued by the laboratory, lack of established policies and procedures, and interview with the facility personnel, the laboratory failed to establish policies and procedures that ensure positive identification of patient's dermatopathology specimens throughout the test reporting process. Findings include: 1. The laboratory performs frozen biopsy interpretations under the sub-specialty of histopathology, with an approximate annual test volume of 2. It is the practice of the laboratory to assign a unique accession number to each frozen biopsy specimen. The unique accession number is included on the patient's slide(s) and the patient's test report. 2. The dermatopathology test report reviewed during the survey (Requisition# P220AP01LS) listed the accession number "FB22-0001, FB22-0002" in the header of the test report. The test report included the diagnosis of two separate specimens as follows: A(1). Squamous Cell Carcinoma (Forehead - Medial) B(2). Squamous Cell Carcinoma (Parietal Scalp - Medial) 3. The test report indicated above failed to positively identify which unique accession number was assigned to specimen A and which unique accession number was assigned to specimen B. 4. The laboratory failed to establish policies and procedures that ensure positive identification and optimum integrity of a patient's frozen biopsy specimen from the time of collection through completion of testing and reporting of results. 5. On September 6, 2022 at 10:40am, the facility personnel acknowledged that the test report indicated above failed to ensure positive identification of the patient's specimens, and confirmed that the laboratory failed to establish policies and

	procedures that ensure positive identification of patient's dermatopathology specimens throughout the test reporting process.
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 lack of written Quality Assessment policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures related to accuracy verification for histopathology testing performed by the laboratory. Findings include: 1. The laboratory performs frozen biopsy interpretations under the sub-specialty of Histopathology. 2. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 3. The facilty personnel interviewed during the survey on September 6, 2022 at approximately 11:30am confirmed that the laboratory failed to have an established written policy specific to the verification of accuracy process for frozen biopsy interpretations performed by the laboratory. 4. The laboratory began patient testing on July 17, 2020. The laboratory interpreted the results of 5 frozen biopsies from July 17, 2020 through September 6, 2022.
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 direct observation of histopathology stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with Mohs and frozen biopsy interpretations, with an approximate annual test volume of 974. 2. During the survey conducted on September 6, 2022, direct inspection of the Hematoxylin reagent, lot #2012126, indicated an expiration date of May 5, 2022. 3. The total number of patients tested using the expired reagent could not be determined at the time of the survey. 4. At approximately 11:55am on 9/06/22, the facility personnel interviewed stated that the expired reagent indicated above was in use at the time of the survey.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, (A) the laboratory failed to include the correct laboratory address where the testing was performed on the final test report; (B) the laboratory failed to include the gross description on pathology test reports issued by the laboratory; and (C) the laboratory failed to include the microscopic description on pathology test reports issued by the laboratory. Findings include: A1. The laboratory performs frozen biopsy interpretations in the subspecialty of histopathology, with an approximate annual test volume of 2. A2. The frozen biopsy test report reviewed during the survey (Accession# FB22-0001, FB22-0002) failed to include the correct laboratory address where the testing was performed. The test report listed the laboratory address as 4500 E. Bell Rd. Ste 150, Phoenix, AZ 85032. A3. At the time of the survey conducted on September 6, 2022, the laboratory address listed in the CLIA database for CLIA# 03D2181402 was 4550 E. Bell Rd. Ste 150, Phoenix, AZ 85032. A4. The facilty personnel acknowledged the laboratory address where the diagnosis was made was incorrect on the frozen biopsy test reports issued by the laboratory. B1. The frozen biopsy test report indicated above failed to include the gross description for each specimen tested {Specimen A(1) and Specimen B(2)}. B2. The gross description (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue) must be included on the pathology test report. B3. The facility personnel acknowledged that the gross description for each specimen was missing from the pathology test report. C1. The pathology test report referenced above included two separate specimens which were identified as A(1) and B(2). C2. No microscopic description of the tissue was included on the pathology test report for specimen A(1). C3. The facility personnel confirmed that the pathology test report reviewed during the survey failed to include a microscopic description for specimen A(1).