Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2181402	01/15/2025
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for the Immunohistochemical (IHC) stain, MART-1, and interview with facility personnel, the MART-1 test procedure failed to include information as required under 493.1251(b). Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 2,350. 2. The laboratory performs the IHC stain, MART-1, on melanoma tissues. Direct observation of the MART-1 stain during the survey indicated the manufacturer as BIO

	SB, lot# 035600125, expiration date 12-01-2026. 3. The MART-1 test procedure reviewed during the survey conducted on 1/15/2025 failed to include the following: - Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. - Microscopic examination, including the detection of inadequately prepared slides. - Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. - Control procedures (See D5441 for specific findings) - Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. - Limitations in the test methodology, including interfering substances - Reference intervals (normal values). - The laboratory's system for entering results in the patient record and reporting patient results. - Description of the course of action to take if the MART-1 stain becomes inoperable 4. The facility personnel interviewed on 1/15/2025 at 11:56 AM confirmed the IHC stain procedure presented for review during the survey failed to include the required information listed above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure for the MART-1 IHC stain and interview with the facility personnel, the laboratory director failed to approve, sign and date the MART-1 test procedure before use. Findings include: 1. The laboratory began using the MART-1 IHC stain in conjunction with the Mohs procedure in the sub-specialty of Histopathology in December 2022. The laboratory's reported annual test volume in the subspecialty of Histopathology is 2,350. 2. The step-by-step MART-1 stain procedure presented for review during the survey conducted on January 15, 2025 failed to include the approval, signature and date of the current laboratory director. 3. The facility personnel interviewed on 1/15/2025 at 11:52 AM acknowledged that the MART-1 step-by-step stain procedure was not signed and dated by the current laboratory director at the time of the survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: Based on lack of temperature records from 1 out of 13 testing dates in November 2023 (11/30/2023) and interview with the facility personnel, the laboratory failed to monitor and document the room temperature of the area where dermatopathology

	reagents are utilized and stored, and failed to monitor and document the temperature of the cryostats used in conjunction with Mohs and Frozen Biopsy testing. Findings include: 1. The laboratory processes specimens and interprets dermatopathology slides in conjunction with Mohs surgery and Frozen Biopsies, with an approximate annual test volume of 2,350. 2. No documentation of the room temperature was presented for review from 11/30/2023, to indicate the laboratory monitored and documented the temperature of the room where dermatopathology reagents are utilized and stored each day of testing. 3. No documentation of the cryostat temperature was presented for review from 11/30/2023, to indicate the laboratory monitored and documented the temperature of the cryostats used on each day of testing. The laboratory utilizes 2 cryostats for specimen processing. 4. A total of 13 patients were tested by the laboratory on 11/30/2023. 5. The facility personnel interviewed on 1/15/2025 at 11:20 AM confirmed that the laboratory failed to monitor and document the cryostat temperatures and the room temperature of the laboratory on 11/30//2023.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on lack of established control procedure documentation for review and interview with the facility personnel, the laboratory failed to establish control procedures for the immunohistochemical (IHC) stain, MART-1. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 2,350. 2. The laboratory performs the MART-1 IHC stain on melanoma specimens, as determined by the diagnosing physician. 3. No evidence was presented for review during the survey conducted on 1/15/2025 to indicate the laboratory established control procedures for the MART-1 stain, including but not limited to, the number, type and frequency of testing control materials. The laboratory began using the MART-1stain in December 2022. 4. The facility personnel interviewed on 1/15/2025 at 11:55 AM confirmed that the laboratory failed to provide documentation of an approved QC procedure for the MART-1 stain.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by:

	Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of the Hematoxylin & Eosin (H&E) staining materials on 1 out of 9 testing dates reviewed during the survey, for intended reactivity and to ensure predictable staining characteristics. Findings include: 1. The laboratory performs Mohs, Frozen Excisions and Frozen Biopsy Interpretations under the subspecialty of Histopathology with a reported annual test volume of 2,350. 2. The laboratory failed to document the acceptability of the H&E stain on 1 out of 9 testing dates (11/30/2023) reviewed during the survey. 3. The laboratory tested 13 patient specimens using the H&E stain on 11/30/2023. 4. The facility personnel interviewed on 1/15/2025 at 11:10 AM confirmed the laboratory failed to document the H&E stain acceptability each day of use for intended reactivity and to ensure predictable staining characteristics on the testing date indicated above.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of Immunohistochemical (IHC) stain records for the MART-1 stain, review of patient test reports and interview with the facility personnel, the laboratory failed to check and document negative reactivity for the MART-1 stain each time of use. Findings include: 1. The laboratory performs testing in the subspecialty of histopathology, with a reported annual test volume of 2,350. It is the practice of the laboratory to perform the IHC stain, MART-1, in conjunction with the Mohs procedure for any specimen previously diagnosed as Melanoma. The laboratory documents the positive reactivity of the MART-1 stain on each patient's Mohs map, each time of use. The laboratory began using the MART-1 stain in December 2022. 2. Two out of two MART-1 test reports (FM23-0397 and FM24-0779) reviewed during the survey failed to include documentation to indicate the laboratory checked the negative reactivity of the MART-1 stain each time of use. 3. No other evidence was provided for review to indicate the laboratory checked and documented the negative reactivity of the MART-1 stain each time of use from December 2022 through the date of the survey, January 15, 2025. 4. The facility personnel interviewed on 1/15 /2025 at 11:40 AM confirmed that the laboratory failed to assess and document the negative reactivity of the MART-1 stain each time of use.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 frozen biopsy pathology reports and interview with the facility personnel, the laboratory failed to include the gross description on 2 out of 4 frozen biopsy reports reviewed during the survey. Findings include: 1. The laboratory performs testing in the subspecialty of histopathology, with an approximate annual test volume of 2,350. 2. Two out of four frozen biopsy pathology reports (FB23-0471 and FB24-0012) failed to include the gross description. 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. 3. The facility personnel interviewed on 1/15/2025 at 10:45 AM acknowledged that the gross description was missing from each pathology test report referenced above. ****This is a repeat deficiency from the previous survey conducted on 9/06/2022.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 lack of Quality Control (QC) documentation for the H&E Stain and the MART-1 stain and interview with the facility personnel, the laboratory director failed to ensure that QC programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. The laboratory director failed to ensure QC policies and procedures are established for the MART-1 IHC stain. (See D5403, D5441 and D5601 for specific findings) 2. The laboratory director failed to ensure QC procedures are maintained for the H&E stain acceptability each day of patient testing. (See D5473 for specific findings) 3. The facility personnel interviewed on January 15, 2025 at 12:05 PM confirmed the laboratory director failed to ensure QC programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 4. The laboratory performs testing in the subspecialty of histopathology with a reported annual test volume of 2,350.