Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2054155	10/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Plastic Surgery Of Arizona	698 E Wetmore Ste 310, Tucson, 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) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 Immunohistochemical (IHC) stains and interview with facility personnel, the IHC test procedure failed to include control procedures for each IHC stain and failed to include procedures for reporting IHC test results. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. The laboratory performs the IHC stains, CK-5, MART-1, SOX-10, and Creutzfeldt-Jakob disease (CJD), on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. The IHC test

	procedure reviewed during the survey conducted on 10/17/23 failed to include control procedures for each IHC stain indicated above. 4. The IHC test procedure reviewed during the survey conducted on 10/17/23 failed to include procedures for reporting IHC test results. 5. The facility personnel interviewed on 10/17/23 at 12:30 PM confirmed the IHC stain procedure reviewed during the survey failed to include control procedures for each IHC stain and failed to include procedures for reporting IHC test results.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on lack of written quality control procedures for Immunohistochemical (IHC) stains, review of the manufacturer's package inserts for IHC stains and interview with the facility personnel, the laboratory failed to determine the control procedures for IHC stains based upon the performance specifications verified by the laboratory. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. The laboratory performs the IHC stains, CK-5, MART-1, SOX-10, and Creutzfeldt-Jakob disease (CJD), on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. It is the practice of the laboratory to use previously tested patient specimens as positive and negative tissue controls for the IHC stains listed above. Reading of the control specimens is performed simultaneously with the patient slide. 4. The manufacturer's package insert for each IHC stain indicated above states, "Positive Tissue Control: ...One positive tissue control for each set of test conditions should be included in each staining run. Previous tissue specimens that have been frozen and freshly cut or in some cases, an individual's own tissue may be used as controls. The tissues used for the positive control should be selected from patient specimens with well-characterized low levels of the positive target activity that gives weak positive staining. If the positive tissue controls fail to demonstrate positive staining, results with the patient specimens should be considered invalid. Negative Tissue Control: The same tissue used for the positive control may be used as the negative tissue control. The variety of cell types in most tissue sections offers internal negative control sites. But this should be verified by the user. The components that do not stain should demonstrate the absence of specific staining, and provide an indication of non-specific background staining. If specific staining (false positive staining) occurs in the negative tissue control sites, results with the patient specimens must be considered invalid." 5. No documentation was presented for review during the survey to indicate the laboratory determined the IHC control procedures for both positive and negative controls based upon the performance specifications verified by the laboratory for each IHC stain. The control procedures must include the frequency, type and number of control materials used for each IHC stain. 6. The facility personnel interviewed on 10/17/2023 at 12:56 PM confirmed the laboratory failed to determine control procedures for the IHC stains as indicated above. 7. The number of patient specimens tested with IHC stains could not be determined at the time of the survey
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of a microscope maintenance policy for review and interview with the facility personnel, the laboratory failed to establish a maintenance policy for the microscope used to read patient slides. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. No maintenance policy was presented for review during the survey for the microscope used to read patient slides. 3. The facility personnel interviewed on 10/17/2023 at 12:10 PM confirmed the laboratory failed to have an established maintenance protocol in place for the microscope.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of positive and negative Quality Control (QC) documentation for Immunohistochemical (IHC) stains from 2021 through the date of the survey on 10/17/2023 and interview with the facility personnel, the laboratory failed to check immunohistochemical stains for positive and negative reactivity each time of use. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 1,500. 2. The laboratory performs the IHC stains, CK-5, MART-1, SOX-10, and CJD, on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 3. No documentation of positive and negative stain acceptability for each IHC stain listed above was presented for review for testing that occurred during 2021, 2022, and 2023 (through the date of the survey conducted on 10/17/2023). 4. The number of patient specimens tested with IHC stains during the timeframe indicated above could not be determined at the time of the survey. 5. The facility personnel interviewed on 10/17/2023 at 12:45 PM confirmed the laboratory failed to check each IHC stain for positive and negative reactivity each time of use during the timeframe indicated above.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 IHC control procedures and IHC control documentation for review for testing that occurred during 2021 through October 17, 2023, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5403, D5425 and D5475 for findings.