Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2163901	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Desert Sky Dermatology Pllc	1688 E Boston Street Suite 101, Gilbert, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2018, 2019 and 2020. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory verified the accuracy of frozen biopsy testing at least twice annually during 2018, 2019 and 2020. 2. The facility personnel confirmed that the laboratory failed to verify the accuracy of frozen biopsy testing at least twice annually since patient testing began. 3. The laboratory tested approximately 2 patients in 2018, 4 patients in 2019 and 4 patients in 2020.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of written policies and procedures for review and interview with the

	facility personnel, the laboratory failed to establish policies and procedures for specimen/slide labeling. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology, with an approximate annual test volume of 1,726. The laboratory reads and interprets slides in conjunction with Mohs testing and frozen biopsy testing. 2. No documentation was presented for review during the survey to indicate the laboratory had established policies in place for slide labeling with regard to Mohs testing. 3. No documentation was presented for review during the survey to indicate the laboratory had established policies in place for slide labeling with regard to Frozen Biopsy testing. 4. The facility personnel confirmed that the laboratory did not have the above referenced policies and procedures in place at the time of the survey conducted on May 13, 2021.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of a written procedure for review and interview with the facility personnel, the laboratory failed to have a written procedure for frozen biopsy testing performed under the sub-specialty of histopathology. Findings include: 1. The laboratory performs dermatopathology testing, including Mohs and the interpretation of frozen biopsies, with an approximate annual test volume of 1,726. 2. No documentation was presented for review during the survey conducted on May 13, 2021 to indicate the laboratory established a written procedure for frozen biopsy testing. The laboratory began testing for the interpretation of frozen biopsies in June 2018. 3. The facility personnel confirmed that the laboratory did not have an established written procedure for frozen biopsy interpretation.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 manual presented during the survey and interview with the facility personnel, the laboratory failed to have a procedure manual that was approved, signed, and dated by the current laboratory director. Findings include: 1. The laboratory's procedure manual presented for review during the survey conducted on May 13, 2021 failed to include the approval, signature and date of the laboratory director. 2. The facility personnel acknowledged that the procedure manual 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) 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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the laboratory's room temperature logs and interview with the facility personnel, the laboratory failed to define the criteria for the room temperature. Findings include: 1. The laboratory performs Mohs surgery slide interpretation with an annual test volume of approximately 1,726. The laboratory began patient testing in September 2017. 2. The laboratory documented the room temperature where the staining reagents are stored and utilized for Mohs slide processing, but there was no policy or indication that a room temperature range had been established. 3. The facility personnel confirmed that the laboratory had not established a room temperature range.