Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1081123	(X3) Date Survey Completed 05/31/2023
Name of Provider or Supplier Southwest Skin Specialists, Llc Dba	**Street Address, City, State** 14506 W Granite Valley Dr #206, Sun City West, 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
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 reagents for the CK-5 Stain past the expiration date. Findings include: 1. The laboratory performs the CK-5 Stain on patient slides in conjunction with dermatopathology testing, with an approximate annual test volume of 9 tests. 2. During the survey conducted on May 31, 2023, direct inspection of the 'IHC Blocker' reagent in use at the time of the survey, lot# 00001524, expiration date 3/20/2022, revealed the reagent was used for patient testing past the expiration date. 3. During the survey conducted on May 31, 2023, direct inspection of the 'CK5 pHRP' reagent in use at the time of the survey, lot# 00001523, expiration date 4/15/2022, revealed the reagent was used for patient testing past the expiration date. 4. The exact number of patient specimens tested with the expired reagents could not be determined at the time of the survey. 5. The facility personnel interviewed on May 31, 2023 at 2:08pm confirmed the expired reagents indicated above were in use on the day 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 review of microscope maintenance records and interview with the facility personnel, the laboratory failed to perform and document the annual preventative maintenance of the microscope used for patient testing under the subspecialty of Histopathology. Findings include: 1. During the survey conducted on May 31, 2023, no documentation was presented for review from 2022 to indicate the laboratory performed and documented annual preventative maintenance on the microscope used for reading patient slides. 2. The facility personnel interviewed on May 31, 2023 at 1: 55pm confirmed there was no documentation of annual preventative maintenance from 2022 for the microscope used by the laboratory to read patient slides under the subspecialty of Histopathology. 3. The laboratory's reported annual test volume under the subspecialty of Histopathology is 2,424.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. 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 CK-5 staining materials each day of use for intended reactivity to ensure predictable staining characteristics. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the sub-specialty of Histopathology, with a reported annual test volume of 2,424. The laboratory performs the CK-5 Stain on certain tissues, if warranted and ordered by the physician who issues the diagnosis. 2. No documentation of the CK-5 stain acceptability was presented for review for testing that occurred during 2021, 2022 and 2023 through the date of the survey conducted on May 31, 2023. 3. The laboratory's reported annual test volume for the CK-5 Stain is 9. 4. The facility personnel interviewed on May 31, 2023 at 1:40pm confirmed the laboratory failed to document the acceptability of the CK-5 Stain, for intended reactivity to ensure predictable staining characteristics, during the timeframe indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records and interview with the facility personnel, the laboratory's QA processes failed to identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory processes and interprets dermatopathology slides from patient specimens for Mohs testing, Frozen Biopsy testing and, if warranted, CK-5 Stain testing. The laboratory's approximate annual test volume is 2,424. 2. The laboratory performs and documents a monthly Quality Assessment (QA) checklist. 3. The laboratory's monthly QA checklists reviewed during the survey from 2021 through April 2023 failed to monitor, identify and correct problems found in the analytic systems. (See D5417, D5433, and D5473 for specific findings) 4. The facility personnel interviewed on May 31, 2023 at 2:15pm confirmed the laboratory's QA processes at the time of the survey failed to identify and correct errors found in the analytic systems.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on lack of test reports for review and interview with the facility personnel, the laboratory failed to provide the test report for one out of two patient records reviewed during the survey. Findings include: 1. The laboratory performs testing in the subspecialty of Histopathology, with an approximate annual test volume of 2,424. The laboratory performs the CK-5 IHC Stain on specimens, if ordered. The laboratory utilizes an electronic medical record (EMR) system to maintain final test reports for patients. 2. No CK-5 IHC Stain test report was presented for review for one out of two patient test records (D.D. from 6-07-22) reviewed during the survey conducted on May 31, 2023. 3. The facility personnel interviewed on May 31, 2023 at 1:40pm confirmed the laboratory failed to enter the patient's test report into the EMR as 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 CK-5 Stain Acceptability records for review for testing that occurred during 2021 through May 31, 2023, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5473 and D5791 for findings.