Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1081123	(X3) Date Survey Completed 10/21/2020
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
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 the laboratory's Mohs log, review of patient slides, review of the electronic test report and interview with the facility personnel, the laboratory failed to follow established procedures to ensure positive identification of patient's dermatopathology specimens. Findings include: 1. The laboratory performs Mohs testing under the sub-specialty of histopathology, with an approximate annual test volume of 3,600. It is the practice of the laboratory to assign a unique case number to each patient's Mohs specimen. The case number is included on the Mohs log, the patient slide(s) and the patient's electronic test report. 2. Review of the electronic test report for patient W.O. from 8/25/20 indicated the Mohs case number as "CMS20-1105". The Mohs log and Mohs slides for this patient indicated the Mohs case number as "CMS20-1108". 3. The facility personnel confirmed that the electronic test report indicated above contained the incorrect specimen ID (case #).
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. (g) The laboratory must document all control procedures performed. 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 histopathology stain, CK-5. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 3,600. 2. The laboratory performs the CK-5 stain (IHCDirect Cytokeratin 5) on certain specimens, as determined by the diagnosing physician. 3. No evidence was presented for review during the survey conducted on 10/21/20 to indicate the laboratory established a control procedure for the CK-5 stain, including the number, type and frequency of testing control materials. The laboratory began using the stain in July 2020. 4. The manufacturer's instructions for the CK-5 stain states, "Positive and negative controls should be run simultaneously with patient specimens." 5. The facility personnel confirmed that the laboratory did not have documentation of an approved QC procedure for the CK-5 stain.
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 staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 3,600. 2. The laboratory performs the CK-5 stain (IHCDirect Cytokeratin 5) on certain specimens, as determined by the diagnosing physician. 3. No documentation of the CK-5 stain acceptability was presented for review for patient testing that occurred on 07/16/20 and 09/10/20. Approximately 2 patients were tested on those dates. 4. The manufacturer's instructions for the CK-5 stain states, "Positive and negative controls should be run simultaneously with patient specimens." 5. The facility personnel confirmed that the laboratory failed to document the stain acceptability on the testing dates indicated above.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of quarterly Quality Assessment (QA) documentation, review of electronic test records and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified with electronic test reports. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 3,600. The laboratory utilizes an electronic medical record (EMR) system to document the test procedure and test results. 2. The laboratory's QA process at the time of the survey conducted on 10/21/20 consisted of a quarterly review of records including the patient consent form, Mohs map and Mohs slides. Approximately 2 patient records from each month were reviewed on a quarterly basis. 3. No documentation was provided for review during the survey to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified with the Mohs test results entered into the EMR. 4. The laboratory failed to correctly identify the Mohs case number in the EMR for one out of four patient records reviewed during the survey. See D5203 for findings. 5. The facility personnel confirmed that the laboratory's established QA procedures failed to monitor, assess and correct problems identified with the test report information entered into the EMR.