

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1089249	(X3) Date Survey Completed 08/25/2026
Name of Provider or Supplier Southwest Skin Specialists, Llc DbA	Street Address, City, State 1331 N 7th Street #250, 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
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 established humidity criteria defined by the laboratory, review of the manufacturer's specifications for the analyzer, and interview with the facility personnel, the laboratory failed to define criteria for the humidity of the area where the Thermo Scientific HM525 NX cryostat is utilized. Findings include: 1. The laboratory utilizes the Thermo Scientific HM525 NX cryostat instrument to process patient tissue for analysis during the Mohs procedure. This testing is performed under the subspecialty of Histopathology with an annual test volume of 825. 2. The manufacturer's specifications for the Thermo Scientific HM525 NX cryostat reviewed during the survey listed an operating relative humidity range of 0% to 60%. 3. The laboratory failed to establish the humidity range for the room where the Thermo Scientific HM525 NX cryostat is utilized. 4. The facility personnel interviewed on 8 /25/26 at 10:00 AM confirmed the laboratory failed to define the humidity criteria for the area where the Thermo Scientific HM525 NX cryostat is utilized.
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 Mohs test reports maintained in the Electronic Health Record (EHR) and interview with the facility personnel, one out of three Mohs test reports reviewed in the EHR failed to list the correct number of Mohs stages performed. Findings include: 1. The laboratory reads and interprets slides in conjunction with the Mohs procedure in the subspecialty of Histopathology with an approximate annual test volume of 825. 2. It is the practice of the laboratory to maintain the Mohs test report (Mohs operative report and Mohs map) in an electronic record system. The total number of stages is documented on the test report (operative note) maintained in the EHR and on the Mohs map. 3. One out of three Mohs test reports (Patient #1: DOS; 4/17/25) reviewed in the EHR during the survey failed to list the correct number of stages. The Mohs log, Mohs map and slides indicated the case had four stages. The Mohs operative report maintained in the EHR stated, "Number of Stages: 6", however the operative report, Mohs log, and slides indicated the case was completed at 4 stages. 4. The facility personnel interviewed on 8/25/26 at 9:30 AM confirmed the Mohs operative report for the patient indicated above failed to list the correct number of stages performed.