Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2029268	03/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Healthy Skin Dermatology	1595 East River Road, Suite 151, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of established Quality Assessment (QA) policies and procedures and interview with the facility personnel, the laboratory's established policy related to the accuracy verification process for dermatopathology testing failed to include information specific to the process performed by the laboratory at the time of the survey conducted on 3/11/2025. Findings include: 1. The laboratory performs the microscopic interpretation (reading/diagnosis) of dermatopathology specimens in the subspecialty of Histopathology, with a reported annual test volume of 4,187. The CMS-209, Laboratory Personnel Form provided for review by the laboratory staff on March 11, 2025 listed two testing personnel. 2. The laboratory's established policy titled, "Proficiency Review of Slides" states, "Healthy Skin Dermatology will send 3-4 Mohs cases for proficiency bi-annually, approximately every 6 months." 3. The policy referenced above failed to include: information specific to the accuracy verification of Frozen Biopsies, information indicating that cases will be sent for review for each physician who reads/interprets dermatopathology specimens (as evidenced by the laboratory's process at the time of the survey), the name and address of the individual or organization who will review the cases, the corrective action steps to take in the event of a noted discrepancy, and the process of reviewing the results once the cases are returned to the lab. 4. The facilty personnel interviewed on 3/11/25 at 11:39 AM confirmed the laboratory's established policy for the accuracy verification process for dermatopathology testing was lacking the information listed above.

D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of established quality assessment (QA) policies and procedures, review of the patient case log for Mohs from 2024 and 2025 and interview with the facility personnel, the laboratory failed to follow their established policy for maintaining a patient case log for testing performed in conjunction with the Mohs procedure for 55 testing days in 2024 and 2025. Findings include: 1. The laboratory's established policy for 'Specimen Handling, Transport, Preservation and Identification' states, "The date of service, Mohs accession number, patient name, type of cancer, location of removal, referring provider, stages, final length, and repair will be logged into the patient case log by the Mohs surgeon, histotechnician or rotating medical assistants." 2. Review of the patient case log from 2024 and 2025 for the Mohs procedure revealed the laboratory failed to document the location, referring provider, final length, and repair type for each Mohs case from 12/28/24 through 3/10/25. 3. The facility personnel interviewed on 3/11/25 at 10:35 AM confirmed the laboratory failed to include all the documentation in the patient case log for Mohs as required by laboratory policy from 12/28/24 through 3/10/25.
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 humidity records for review from 1/02/2023 through 3/11/2025 and interview with the facility personnel, (A) the laboratory failed to monitor and document the ambient humidity of the room where histopathology specimens are processed, and (B) the laboratory failed to monitor and document the temperature of the room where patient testing occurred on 1 out of 17 testing dates in February 2025. Findings include: 1. The laboratory performs patient testing in the subspecialty of Histopathology with an annual test volume of 4,187. The laboratory performs testing on Monday through Friday, excluding holidays. A2. The laboratory utilizes two cryostats, Leica 1520 and Leica 1850, to process dermatopathology specimens. The manufacturer's environmental operating requirements for each cryostat indicates an ambient humidity range of 0-60%. A3. The laboratory failed to monitor and document the ambient humidity of the room where specimen processing occurred on each testing day from 1/02/23 through the survey date on 3/11/25. A4. The facility personnel interviewed on 3/11/25 at 11:17 AM confirmed the laboratory failed to

	monitor and document the ambient humidity as indicated above. B1. The laboratory failed to monitor and document the room temperature on 1 out of 17 testing dates in February 2025 (2/08/25). B2. The laboratory tested histopathology specimens from 11 patients on 2/08/25. B3. The facility personnel confirmed that laboratory staff failed to monitor and document the room temperature of the laboratory on 2/08/25.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for review and interview with the facility personnel, the laboratory failed to document the acceptability of Hematoxylin & Eosin (H&E) staining materials, for intended reactivity and to ensure predictable staining characteristics on 1 out of 7 testing dates reviewed during the survey Findings include: 1. The laboratory performs testing under the subspecialty of Histopathology with a reported annual test volume of 4,187. 2. The laboratory failed to document the acceptability of the H&E stain on 1 out of 7 testing dates (2/07/25) reviewed during the survey. 3. The laboratory tested 10 patient's specimens using the H&E stain on 2/07/25. 4. The facility personnel interviewed on 3/11/2025 at 11:24 AM confirmed the laboratory failed to document the H&E stain acceptability each day of use for intended reactivity and to ensure predictable staining characteristics on the testing date indicated above.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of Mohs and Frozen Biopsy pathology test reports on March 11, 2025 and interview with the facility personnel, the laboratory failed to maintain complete test records for two out of four Mohs cases reviewed and the laboratory failed to include the gross description on one out of three frozen biopsy reports reviewed during the survey. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology with a reported annual test volume of 4,187. It is the practice of the laboratory to maintain test records in an Electronic Health Record (EHR) system. 2. Two out of four Mohs maps (specimen ID# 34479 from 2/07/24 and #37123 from 2/03/25) failed to include the total number of Mohs stages, including the drawing of the specimen at each stage and the stage in which the specimen was cleared of cancerous cells. 3. The facility personnel interviewed on 3/11/25 at 10:20 AM acknowledged that the Mohs maps scanned into the EHR failed to include the second page of the map for the cases

	indicated above. 4. One out of three Frozen Biopsy pathology reports (JCRREXC- 08) reviewed during the survey failed to include the gross description of the tissue examined. 5. The facility personnel interviewed on 3/11/2025 at 10:53 AM confirmed that the gross description for case# JCRREXC-08 was missing from the frozen biopsy test report.