Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2029268	01/20/2021
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
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 the stain reagent, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient slides in conjunction with Mohs testing, with an approximate annual test volume of 650 tests. 2. During the survey conducted on January 20, 2021, direct inspection of the Hematoxylin reagent, lot #020819, indicated an expiration date of 08/08/20. 3. Patient testing occurred on approximately 25 dates since the reagent expired. The total number of patients tested using the expired reagent could not be determined at the time of the survey. 4. The facility personnel confirmed that the expired reagent indicated above was still in use on the day of the survey.
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 patient 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 650. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occurred on 04/08/2019. Approximately 1 patient was tested on that date. 3. The facility personnel confirmed that the laboratory failed to document the stain acceptability on the date indicated above.
D5787	TEST RECORDS CFR(s): 493.1283(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 patient test records and patient slides associated with Mohs testing and interview with the facility personnel, the laboratory failed to indicate the correct testing date on the patient slides. Findings include: 1. The laboratory performs patient testing under the sub-specialty of histopathology, with an approximate annual test volume of 650. It is the practice of the laboratory to label the patient slide with the date and Mohs Case number. 2. Review of the Mohs slide for patient A.H., case# 28973, indicated the testing date as 04/04/19. The Mohs log and electronic note for this patient indicated Mohs testing was performed on 04/08/19, not 04/04/19. 3. The facility personnel confirmed that the Mohs slide indicated above was labeled with the incorrect testing date.