Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2289913	08/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Healthy Skin, Pllc	2550 S Telegraph Road Suite 104, Bloomfield Hills, MI	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation, record review and interview with Mohs Technician, the laboratory failed to follow safety procedures per laboratory policy. Findings include: 1. The Surveyor observed on 08/07/2024 at 9:41 am that the laboratory did not have a fume hood for processing specimens. 2. Record review of laboratory policy and procedures indicated in chapter "Coverlsipping (Hand Method)", section "Procedure Notes", stated "...Coverslipping should be done under a fume hood." 3. An interview with Mohs Technician, on 08/07/2024 at 11:51 am confirmed the laboratory does not have a fume hood.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with Mohs Technician, the laboratory failed to establish competency assessment policies to assess staff competency. Findings include: 1. A review of the laboratory's policies and procedures revealed that

	laboratory did not have a competency assessment policy. 2. An interview with Mohs Technician on 08/07/2024 at 11:25 am confirmed that laboratory did not establish a competency assessment policy.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with Mohs Technician, the laboratory failed to label secondary containers loaded on Expredia Linistat for staining laboratory slides. Findings include: 1. The Surveyor observed Expredia Linistat slide stainer with unlabeled wells of stains on 08/7/2024 at 9:45 am. 2. The Surveyor requested source bottles of stains from Mohs Technician on 08/7/2024 at 9:45am and determined source contents in secondary containers were expired. Refer to tag D5417. 3. An interview with Mohs Technician, on 08/7/2024 at 9:45am confirmed that secondary containers in use were not labeled with source contents..
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 observation, and interview with Mohs Technician, the laboratory failed to ensure stains, coverslipping medium, and optimal temperature cutting (OTC) compound were not used beyond their expiration dates. Findings include: 1. Surveyor observed expired reagents in laboratory on 08/07/2024 at 9:40 am: a. 12 of 12 OTC media with an expiration date of 6/30/2024. b. 2 of 2 bottles of stain Eosin Y (1) Stain expiration date of 1/31/2024 and hematoxylin (1) stain with an expiration date of 7/31 /2024) 2. 1 bottle of CytoSeal - X coverslipping glue with an expiration date of 06/17 /2024. 3. An interview with Mohs Technician at on 8/7/24 at 9:45 am confirmed all reagents listed above were available for use and expired.
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 record review and interview with Mohs Technician, the laboratory failed establish maintenance procedures for the Expredia Linistat slide stainer and Avantik Cryostat. Findings include: 1. Record review of the laboratory procedure manual revealed that a procedure for maintenance was not present for Expredia Linistat slide stainer or Avantik Cryostat. 2. An interview with Mohs Technician on 08/7/2024 at 11: 51 am confirmed maintenance procedures had not been established.
D5805	TEST REPORT CFR(s): 493.1291(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 record review and interview with Mohs Technician, the laboratory failed to include laboratory name and address on the patient test report for 3 (#1-3) of 3 patient test reports reviewed: 1. Record review of 3 patient test reports revealed that laboratory name and address were not listed for the following patients: a. Patient 1 received histopathology testing on 11/15/2023. b. Patient 2 received histopathology testing on 04/24/2024. c. Patient 3 received histopathology testing on 07/31/2024. 2. An interview with Mohs Technician on 08/07/2024 at 11:51 am confirmed laboratory name and address were missing from patient test reports.