Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0685091	09/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Skin Md	4711 Golf Rd, Skokie, IL	

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 direct observation, record review, and an interview with the testing personnel (TP); the laboratory failed to establish and observe safety procedures to ensure protection from chemical hazards, affecting 2 TP. Findings: 1. On 09/16/2020 at 10:10 AM during a tour of the Mohs laboratory (located in a converted storage or patient examining room), the surveyor observed; * 1 (one) table top Rankin Auto Stainer. * Under the autostainer is 1 (one) flammable Chemical Safety Cabinet. The safety cabinet contained the following chemicals: Alcohol, Xylene, Eosin, and Hematoxylin. * The Autostainer was not situated under a chemical exhaust fume hood; and * There were no visible ventilation vents to suction away possible escaping vapors. The Hematoxylin and Eosin (H & E) procedure, the employee files, and the material safety data sheets (MSDS) for the above chemicals were reviewed. 2. The H & E procedure that the Rankin Auto Stainer was programmed to perform uses the chemical Xylene. 3. The MSDS for Xylene states the following under Section 2: Hazards Identification H226 - Flammable liquid and vapor H312+H332 - Harmful in contact with skin or if inhaled. H351 - Suspected of causing cancer. P260 - Do not breathe mist, spray, vapor, gas. P271 - Use only outdoors or in a well-ventilated area. P273 - Avoid release to the environment. 4. The employee files revealed 2 TP performing the H & E procedure in the laboratory. 5. The laboratory failed to provide the required ventilation needed to ensure that 2 out 2 TP were not exposed to the dangerous Xylene vapors when staining tissue. 6. On an Initial survey conducted on 09/16/2020 at 11:15 AM, the TP confirmed the above findings.

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, manual review, and an interview with the testing personnel (TP), the laboratory failed to ensure supplies are not to be used when they have exceeded their expiration date. Findings Include: 1. On 09/16/2020 at 10:10 AM during a tour of the laboratory, the surveyor observed the following expired tissue marking and margin Inking dyes: * Orange - Lot# 020519 - expiration date 02/05 /2020, * Yellow - Lot# 031119 - expiration date 03/11/2020, * Red - Lot# 022219 - expiration date 02/22/2020, * Green - Lot# 022019 - expiration date 02/20/2020, * Black - Lot# 032519 - expiration date 03/25/2020, and * Blue - Lot# 040219 - expiration date 04/02/2020. 2. The laboratory's manual failed to include a written method that would ensure reagents and supplies are not used pass their expiration dates. 3. On an Initial survey conducted on 09/16/2020 at 11:15 AM, the TP confirmed the above findings.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and an interview with the testing personnel (TP), the laboratory failed to document all control procedures performed, as specified in the specialty of Histopathology, affecting 6 out 6 patients. Findings Include: 1. The laboratory manual, Mohs surgery patients' logs, and quality control (QC) worksheets were reviewed. 2. The Mohs logs from the dates of 04/27/2020 and 07/06/2020 were selected for QC record review. 3. The QC worksheets revealed that the laboratory failed to document the following information on the 2 selected test dates: *The identification of the slide used to assess stain quality or QC-slide; and *The lot numbers, date prepared/opened, and expiration dates of the reagents and stains used to perform the Hematoxylin and Eosin (H & E) tissue staining procedure. 4. The laboratory processed surgery tissue from 3 patients on 04/27/2020 and 3 patients on 07 /06/2020. 5. The laboratory manual and QC worksheet failed to include a written method that would ensure the required information for its reagents and stains are documented each day of tissue processing and staining. 6. On an Initial survey conducted on 09/16/2020 at 11:15 AM, the TP confirmed the above findings.