Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2189388	12/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates & Surgery Center Williamson	150 E Second Avenue, Williamson, WV	

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
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures (P&P), the Safety Data Sheets (SDS) for the chemical inventory, a tour of the laboratory, and an interview with the laboratory manager, the laboratory failed to ensure a ventilation system that removes vapors and fumes from the use of chemicals for the processing of MOHs specimens. Findings: 1. A review of the written P&P identified a "Chemical Hygiene Plan" that listed the workplace chemicals and the PPE required. The PPE listed as required for CitraClear and Select Eosin included "respiratory protection" and "vent". 2. A review of P&P identified a "Air Vent/Fume Hood Policy" that stated "The air vent or fume hood should be turned on as soon as the lab is open for operation, should remain on during operating hours." 3. A tour of the laboratory identified no air ventilation system or fume hood in the small space that the processing of slides with Select Eosin and CitraClear occur. 4. A review of SDS sheets for CitraClear and Select Eosin identified both chemicals as having Hazard Statements and Precautionary Statements of "do not breathe vapors". 5. During an interview with the laboratory manager, on 12/17/20 at approximately 10:40 AM, the laboratory manager stated there was no ventilation system or fume hood for the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory written policies and procedures (P&P) and an interview with the laboratory manager, the laboratory failed to establish a (b)(14) description of the course of action to take if a test system becomes inoperable. Findings: 1. A review of written P&P identified no P&P regarding the course of action to take when the test system, Cryostat, becomes inoperable. 2. During an interview with the laboratory manager, on 12/17/20 at approximately 11:00 PM, the laboratory manager stated the process used when the Cryostat is down and that the course of action is not written in the P&P of the laboratory.