Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1032562	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Skin Care Specialty Physicians Llc	1447 York Road Suite 301, Lutherville, MD	

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
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 review of the written procedure manual, interview with the medical assistant and the laboratory director, the laboratory did not have written procedures for all areas of the laboratory. Findings: 1. The laboratory had a power outage on the night of March 5, 2019. 2. On March 6, 2019, the day of patient testing the cryostat was warm and the temperature was not in the range of -20 to -30 Degrees Celsius. 3. The medical assistant and the laboratory director stated that to bring the cryostat up to optimal temperature quickly they lined the bottom of the machine with containers of liquid nitrogen to increase the temperature. 4. The laboratory director stated that he

	did not have written procedures for rapidly increasing the cryostat when the temperature is not within optimal range.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the written procedure manual and interview with the medical assistant , the laboratory did not document the temperature when performing special staining. Findings: 1. The laboratory did not document the temperature of the slide warmer when preparing special stained slides . 2. The medical assistant stated that they don't prepare special stained slides that often and the warmer shows the digital temperature while performing the test. 3. The medical assistant confirmed that the slide warmer temperature is not documented when performing special staining procedures.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature records and interview with laboratory personnel, the laboratory did not perform all the steps needed to correct laboratory errors. Findings: A. 1. The laboratory cryostat #1 and #2 had a temperature reading of "0" on March 6, 2019. 2. The medical assistant stated that the power went out the night before. 3. The cryostat temperature range should be between -20 to -30 Degrees Celsius. 3. The laboratory did not read the cryostats temperature again throughout the day and document to ensure the machines maintained the correct temperature. 4. The medical assistant stated that cryostat #1 was at the correct temperature when performing patient testing and confirmed that neither cryostat temperature was taken again throughout the day and documented. B. 1. The laboratory refrigerator had a temperature reading on September 24, 2018 of 24 Degrees Celsius and on August 6, 2018 of 25 Digress Celsius. 2. The refrigerator range should be between 2-8 Degrees Celsius. 3. The medical assistant stated that the refrigerators are unplugged sometimes

	when housekeeping comes to clean. 4. The laboratory did not read and document the refrigerator temperature again throughout the day to ensure the refrigerator maintained the correct temperature 5. The medical assistant confirmed that the refrigerator temperature was not read and documented again throughout the day to ensure the refrigerator maintained the correct temperature
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on observation of laboratory personnel performing grossing of tissue samples and interview with the laboratory director (LD), the laboratory director did not ensure that all testing personnel received the appropriate education prior to perfuming the test. Findings: 1.. The medical assistant was observed performing tissue grossing on the day of the survey around 10:30 AM. 2.. The grossing procedures included the cutting and inking of tissue samples 3.. The tissue was acquired from MOHS procedures that are performed by the laboratory director. 4. The medical assistant stated that she is taking classes but has not received the required credits needed to perform grossing procedures. 5. The medical assistant stated the LD had shown her what she needs to do to properly perform tissue grossing. 6. The LD stated that he will now perform the grossing in the procedure room and once the grossing procedures are completed he will give the tissue to the medical assistant to prepare the slides.