Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0941746	04/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Western Dermatology Consultants Pc	10151 Montgomery Blvd Ne Bldg 1 Ste A, Albuquerque, NM	

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
D0000	Based upon the onsite recertification survey conducted on 04/11/2022, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on observation and interview with the Practice Manager, the laboratory failed to monitor, document, and define the room temperature range to ensure long-term preservation of the histopathology slides. Findings included; 1. Tour of the laboratory on 04-11-22 at 2:16 pm revealed the laboratory failed to monitor and document the temperature and the humidity of the room in which histopathology slides were stored. 2. During an interview with the Practice Manager and the Front Office Manager on 04-11-22 at 2:30 pm, they confirmed that they did not have a thermometer in the laboratory and that they had not been monitoring and documenting the temperature.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of the Peer Quality Assurance documentation and interview with

	the Practice Manager, the laboratory failed to define the acceptability for verifying accuracy of Mohs examinations twice annually in a written procedure. 1. Review of the Form titled "Peer Quality Assurance Review" for 2019, 2020, and 2021, revealed that the forms lacked the raw data, showing verification of key components of comparison regarding the gross examination and the test reporting. 2. During an interview with the Laboratory Practice Manager and the front Office Manager on 04-11-22 at 3:30 pm, the surveyor asked for the raw data showing the key components for the comparison of the MOHs cases listed on the review forms and found it had not been documented. This verified the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the review of records and interview with the Practice Manager, the laboratory failed to ensure a written procedure manual for Mohs examinations was available to personnel. Findings are: 1. Review of the records revealed there were no written policies and procedures for Mohs examinations performed in the laboratory. 2. During an interview with the Practice Manager, on 04-11-22 at 3:05 pm she stated, "I cannot locate the policies because they might have been archived."
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 observation, and interview with staff, the laboratory failed to monitor, document and define the temperature and humidity of the room in which reagents and equipment were stored for 2019, 2020, and 2021. Findings included; 1. Tour of the laboratory on 04-11-22 at 2:16 pm revealed the laboratory failed to monitor and document the temperature and the humidity of the room in which reagents and equipment were stored. The following reagents and equipment had Manufacturer's temperature storage requirements and were stored in the laboratory; A. Eosin-Y Alcoholic, 2-1 gal bottles, Lot #112277. Expiration date = 10/2023 - Manufacturer's temperature storage requirement listed on bottle was 15C-30C. B. Hematoxylin Solution, 2-1 gal bottles, Lot #112277. Expiration date = 10/2023 - Manufacturer's temperature storage requirement listed on bottle was 15C-30C. C. The Avantik QS12 Cryostat had the following Manufacturer's requirements; a. Temperature (Recommended Operation) requirement of +15C to +30C (+59F to + 86F). "Note:

	Performance may deteriorate when operated outside this range". b. Temperature (Transport and Storage) requirement of -20C to +50C (-4F to 122F). c. Relative Humidity - "Max. 60% RH up to 30C". 2. During an interview with the Practice Manager and the Front Office Manager on 04-11-22 at 2:30 pm, they confirmed that they did not have a thermometer in the laboratory and that they had not been monitoring and documenting the temperature.