Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0113432	05/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Westwood Dermatology	390 Old Hook Road, Westwood, NJ	

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 surveyor observation of the laboratory reagents, the lack of a flammable cabinet and interview with the Techincal Supervisor (TS), the laboratory failed to ensure protection from chemical and physical hazards at the time of survey. The finding include: 1. All flammable and inhalation risk reagents were not kept in a flammable cabinet. 2. All flammable and inhalation risk reagents were kept under the laboratory sink and ancillary cabinets. 3. The TS confirmed on 5/2/23 at 2:00 pm that the laboratory did not ensure protection from chemical and physical hazards.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on surveyor review of Procedure Manual (PM) Staining station (SS) and interview with the Techincal Supervisor (TS), the laboratory failed to include the dates of initial use and discontinuance for staining procedures on the date of survey. The findings include: 1. The PM and the SS had five different histopatholoy staining procedures for Mohs testing in the PM. 2. Five out of five of the staining procedures

	did not have dates of initial use and or discontinuance. 3. The TS confirmed on 5/2/23 at 2:00 pm the laboratory failed to include the dates of initial use and discontinuance for staining procedures.
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: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Supervisor (TS), the laboratory failed to have a complete procedure for "Slide Storage" 4/15/21 to the date of the survey. The findings include: 1. The procedure for "Slide Storage" did not define a retention time for histopathology slides. 2. The TS confirmed on 5/2/23 at 1:30 pm that the laboratory did not have a complete procedure for "Slide Storage" . b) Based on surveyor review of the Procedure Manual (PM), Cryostat Temperature Log (CTL) and interview with the Technical Supervisor (TS) the laboratory failed to follow their procedure for Cryostat Temperature Range (CTR) from 4/15/23 to the date of survey. The finding includes: 1) The PM stated the CTR was 20-25 C. 2) the CTL had the CTR as 20-30 C. 3) The TS confirmed on 5/2 /23 at 1:35 the laboratory failed to follow their procedure for CTR.
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 the lack of Temperature Log (TL), review of the Operators Manual (OM) for the progress capture Pro 2.7 Jenoptick camera, AXICSKOP 40 microscope and interview with the Technical Supervisor (TS), the laboratory failed to monitor room temperature and humidity range where the Professional component (PC) for Histopathology tests are performed from 4/15/21 to the date of the survey. The finding include: 1. The OM defined the acceptable temperature and humidity range for the aforementioned equipment as 5%-80% humidity and 20-75 F. 2. There was no TL in the office where PC was being performed. 3. The TS confirmed on 5/2/23 at 1:35 pm that an acceptable range was not defined.
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 surveyor review of the Procedure Manual (PM) and interview with the Techincal Superisor (TS), the laboratory did not establish a maintenance protocol for the microscope on the date of survey. The TS confirmed on 5/2/23 at 1:30 pm the laboratory did not have a maintenance procedure in the PM.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Supervisor (TS), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements at the time of the survey. The TS confirmed on 5/2/23 at 2:30 pm that a CA procedure was not established.