Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0113432	09/10/2024
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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Specimen Transports Log (STL) and interview with Testing Personnel (TP), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems for Histopathology tests from 7/1/24 to 9/10/24. The finding includes: 1. The PM states "Specimens are picked up at the doctor's office and counted by the doctor's secretary and the driver before leaving the office. Initials of both parties are included on the master sheet. Driver brings back specimens to the lab and each separate doctor's specimens are again recounted by the in charge technician at the lab and the master sheet is again initialed by said person." 2. The STL did not have any initials or signatures in the designated column. 3. TP #1 as listed on the CMS 209 form confirmed on 9/10/24 that the laboratory failed to follow its procedure for specimen accessioning and specimen pickup.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by:

	Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to record discontinuance dates for procedures not in use in the laboratory from 5/2/23 to 9/10/24. The finding includes: 1. TP #1 as listed on the CMS 209 form stated that the procedure for "Water Testing" was no longer being performed. 2. The procedure did not have a written discontinuance date. 3. TP #1 as listed on the CMS-209 form confirmed on 9/10/24 at 12:15 pm that discontinuance dates were not documented.
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 surveyor review of the room humidity records and interview with the Testing Personnel (TP), the laboratory failed to record the actual humidity percentage of the room on each day of patient testing from 1/1/24 to 9/10/24. The finding includes: 1. The room humidity records only had the testing personnel initials as evidence of being in acceptable range and did not have the actual humidity percentage. 2. The acceptable humidity range on the daily temperature record was indicated as 5%-80% 2. The TP #1 as stated on the CMS 209 form confirmed on 9/10 /24 at 1:35 PM, the laboratory did not record the actual room humidity percentage on each day of patient testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of th Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) did not establish a Quality Assurance (QA) procedure for verifying manually entered results into the Electronic Media Record (EMR) from 5/2/23 to 9/10/24. The finding includes: 1. The laboratory did not have a procedure for verifying manually entered results into the EMR. 2. The TP#1 as stated on CMS-209 form confirmed on 9/10/24 at 1:45 PM, the LD did not establish a procedure for verifying manually entered results into the EMR.