Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 31D0863351	**(X3) Date Survey Completed** 05/10/2023
Name of Provider or Supplier Dermatology Center Of North Jersey	**Street Address, City, State** 1033 Clifton Ave, Clifton, 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**
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 lack of a Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to have a procedure for Histopathology Biannual Assessment (BA) on the date of survey. The TP confirmed on 5/10/23 at 2:00 pm that the laboratory did not have the aforementioned procedure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of the Flammable Cabinet and interview with the Testing Personnel (TP), the laboratory used expired Hematoxylin reagent and red tissue marking dye for Histopatholgy testing on 5/10/23. Approximately 8 patient were testing. The TP confirmed on 5/10/23 at 1:30 pm that the laboratory used expired reagent.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to maintain a Quality Control (QC) program for Hematoxilyn and Eosin (H&E) stain reaction on the date of survey. The TP confirmed on 5/10/23 at 1:45 pm that a QC program was not maintained.
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 the lack of a laboratory Procedure Manual (PM) and interview with the Testing Personnel (TP) , the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services for Histopathology tests provided on the date of survey. The TP confirmed on 5/10/23 at 1:45 pm that a QA program was not established.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 the lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP) , the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel on the date of survey. The LD confirmed on 5/10/23 at 1:00 pm that a CA procedure was not established.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

	This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Testing Personnel (TP), Laboratory Director (LD) failed to have an approved PM for Histopathology testing from on the date of survey. The TP confirmed on 5/10/23 at 1:10 pm that the LD did not ensure an approved PM was available.