Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0863351	06/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Center Of North Jersey	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: (a) Based on surveyor review of the Procedure Manual (PM), observation of the Automated Staining Station (ASS) and interview with the Testing Personnel (TP), the laboratory failed to follow Mohs Staining Procedure from 5/3/18 to the date of the survey. The finding includes: 1. The ASS in the laboratory did not correspond with the staining procedure in the PM. 2. The PM stated five dips for 100% alcohol but the ASS had four. 3. The TP #2 listed on CMS form 209 confirmed on 6/3/21 at 12:15 pm that PM procedure did not match with ASS. Note: This is a repeat deficiency Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Quality Control (QC) of Stains by Pathologist from January 2020 to the date of the survey. The finding includes: 1. The PM stated the pathologist will review the Hematoxylin and Eosin (H&E) stain and note review on the Technical Labs Slide Stain Log worksheet. 2. The Technical Labs Slide Stain Log worksheeet was not found in the laboratory. 3. The OM confirmed on 6/3/21 at 12:45 pm that the laboratory did not follow the PM.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with

	each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from January 2020 to the date of survey. The findings include: 1. The laboratory did not document H&E stain QC reaction for reading of biopsy slides. 2. The laboratory read and reported approximately 300 patient slides. 4. The OM confirmed on 6/3/21 at 1:40 pm that the laboratory did not document H&E QC stain reaction.
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 Office Manager (OM), the Laboratory Director failed to maintain a Quality Control (QC) program for Hematoxilyn and Eosin (H&E) stain reaction from January 2020 to the date of survey. The OM confirmed on 6/3/21 at 1:40 pm that a QC program was not maintained.