Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0119315	01/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Center Of Washington Township Pc	100 Kings Way East, Sewell, 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 surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to have a procedure for Biannual Assessment (BA) on the date of survey. The TP confirmed on 1/4/23 at 1:00 pm that the laboratory did not have the aforementioned procedure.
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 Log (QCL) and interview with the Testing Personnel (TP), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from 10/28/21 to the date of survey. The findings include: 1. The laboratory did not document H&E stain Quality Control reaction on

	the QCL for reading of Moh's slides. 2. The laboratory read and reported approximately 1900 patient slides. 3. The TP confirmed on 1/4/23 at 12:40 pm that the laboratory did not document H&E QC stain reaction.
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 Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements for Moh's testing from 3/28 /2018 to the date of the survey. The TP confirmed on 1/4/23 at 1:40 pm that a CA procedure was not established.