Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2145336	08/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology, Pc	368 Lakehurst Road, Toms River, 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) and interview with the Clinical Operation Coordinator (COC), the laboratory failed to have applicable procedure for Quality Assurance Plan (QAP) from May 2018 to the date of survey. The findings include: 1. The QAP procedure step # 6 and 11 were not applicable for histopathology testing. 2. The laboratory had monthly checklist for QAP which had Proficiency Testing (PT) and personnel requirements but the laboratory did not perform PT and personnel requirements every month and was checked off as it was done. 3. The COC confirmed on 8/22/18 at 11:00 am that the QAP procedure was not applicable for the laboratory. b) Based on surveyor review of the PM, Quality Control (QC) Manual, Obervation of Staining Station (SS) and interview with the COC, the laboratory failed to assure that Hematolylin and Eosin Staining Procedure (H&ESP) was followed from April 2018 to the date of survey. The fidnings include: 1. The H&ESP did not mentioned use of 95% alcohol and SS did not have those jars but the H&E QC and Maintenence log sheet had two times new reagent and one time rotated for 95 % alcohol. 2. The flammable cabinet had two bottles of 95% alcohol with opened date but COC stated she does not know if the laboratory used it. 3. The laboratory could not confirm the use of 95% alcohol. 4. The COC confirmed on 8/22 /18 at 11:00 am that the laboratory did not follow H&ESP.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on lack of Maintenance Records (MR), review of LinistatAutomated Stainer (LAS) Manual and interview with the Clinical Operation Coorinator (COC), the laboratory failed to perform and document and establish frequency of performance checks from April 2018 to the date of the survey. The COC confirmed on 8/22/18 at 10:45 am that the laboratory did not perform maintenance on the LAS.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Clinical Operations Coordinator (COC), the laboratory failed to ensure that the FR included all the required information from April 2018 to the date of survey. The findings include: 1. A review of FR revealed that the address of the laboratory where tests were performed was not on FR from June 2018. 2. Mohs maps attached with the FR did not have the name and address of the facility where testing was performed from April 2018. 3. The COC confirmed on 8/22/18 at 10:45 am that FR did not have all the required information.