Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2141911	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology, Pc	4 Paragon Way, Freehold, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Clinical Coordinator (CC), the laboratory failed to perform CA accurately on one of one Histotech on July 29, 2018. The findings include: 1. The CA documentation sheet did not include how CA was accessed, what and when records were reviewed. 2. The CA form had procedures which were not performed in the laboratory and was assessed as "Y". 3. The CC confirmed on 8/28/18 at 12:30 pm that CA was not done accurately.
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 Clinical Coordinator (CC), the laboratory failed to have applicable procedure for Quality Assurance Plan (QAP) from January 2018 to the date of survey. The findings include: 1. The QAP procedure step # 6, 7, 8, 11, and 12 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 CC confirmed on 8/28/18 at 1:15 pm that the QAP procedure was not applicable for the laboratory.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based surveyor review of the Accession Log (AL) and interview with the with Clinical Coordinator (CC), the laboratory failed to identify who prepared Mohs slides from January 2018 to the date of survey. The CC confirmed on 8/28/18 at 12:40 pm that there was no identity of personnel performing testing.
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 Coordinator (CC), the laboratory failed to ensure that the FR included all the required information from January 2018 to the date of survey. The finding includes: 1. Mohs maps attached with the FR did not have the name and address of the facility where testing was performed. 2. The CC confirmed on 8/28/18 at 1:00 pm that FR did not have all the required information.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Biannual Assessment (BA) records and interview with the Clinical Coordinator (CC), the Laboratory Director (LD) failed to ensure that results of Histopathology tests received from the reviewer were reviewed and evaluated for 2018. The CC confirmed on 8/28/18 at 1:00 pm that the BA records were not reviewed and evaluated.