Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2185903	05/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology, Pc	105 Raider Blvd, Hillsborough, 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), observation of Staining Station (SS) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Hematoxyilin-Eosin (HE) staining from 2/3/22 to the date of the survey. The findings include: 1. The PM stated step 10 "10 seconds Eosin" but the SS had 95% alcohol 2. The PM steted step 11 "10 seconds 100 alcohol" but the SS had Eosin. 3. The PM stated step 12 "10 seconds 100 alcohol" but the SS had 95% alcohol. 4. The PM stated step 13 "10 seconds 100 alcohol" but the SS had 95% alcohol. 5. The OM confirmed on 5/21/24 at 10:30 am that the laboratory did not follow the PM.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs (TL) and interview with the Office Manager (OM), the laboratory did not document corrective action taken when the Cryostat Temperature (CT) was out of range in the calendar year 2022. The findings include: 1. A review of the TL revealed that CT was outside the established range: a. 3/6/22, 5/4/22, 6/1/22, 9/7/22, and 11/16/22 2. There was no documented evidence of corrective action taken. 3. The OM confirmed on 5/21/24 at 11:00 am the laboratory did not document corrective action.