Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1029392	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology Group	822 Pine Street Suite 2a, Philadelphia, PA	

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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the assistance general manager (AGM), the LD failed to provide overall management and direction in accordance with 42 CFR 493.1445 from 08/30/2022 to 05/14/2024. Findings include: 1. The laboratory director failed to ensure that quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to 6094. 2. The laboratory director failed to establish and maintain competency assessment for each supervisor and laboratory personnel involved in preanalytical, analytical, and post analytical phases of testing. Refer to D6103. 3. The laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for each test system. Refer to D6095.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of the Quality Assurance policy, Monthly Patient Quality Assurance Checklists, and interview with the Assistant General Manager (AGM), the laboratory

	director (LD) failed to ensure quality assessment (QA) programs were followed to assure the quality of laboratory services provided from 08/30/2022 to 05/14/2024. Findings Include: 1. The laboratory's Quality Assurance procedure states, "The lab director will also review and sign off the checklist monthly." 2. On the day of survey, 05/14/2024 at 11:30 am, review of the Monthly Patient Quality Assurance Checklist revealed the LD failed to review and sign off the monthly QA checklists for the following 8 of 16 months from September 2022 to December 2023. 2022- September, October, November, and December 2023- April, May, June, and December 3. The AGM confirmed the findings above on 05/14/2024 around 1:00 pm. ****** Repeat Deficiency******
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on lack of documentation, review of procedure manual, and interview with the Assistant General Manager (AGM), the laboratory director (LD) failed to ensure the daily maintenance for 1 of 1 Cryostat was documented when macroscopic histopathology examinations were performed in 2023. Findings include: 1. The laboratory's Cryostat Maintenance manual stated "the machine is wiped daily with dry gauze, to collect waste material Then wiped with gauze containing 100% alcohol to disinfect. Wiped again with a dry gauze and ready for Next Day." 2. On the date of survey, 05/14/2024 at 12:00 pm, the laboratory failed to provide documentation for the daily maintenance performed on 1 of 1 Avantik QS-12 Cryostat when histopathology examinations were performed in 2023. 3. The AGM confirmed the findings above on 05/14/2024 at 1:00 pm.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 review of procedure manuals and interview with the Assistant General Manager (AGM), the laboratory director (LD) failed to establish and follow a competency assessment procedure to assess 1 of 1 Clinical Consultant (CC), 1 of 2 Technical Supervisors (TS) and 1 of 1 testing personnel (TP) for their supervisory and testing responsibilities for histopathology examinations performed from 8/30/2022 to the day of survey. Findings Include: 1. On the day of survey, 05/14/2024 at 11:54 am, the laboratory could not provide a competency assessment procedure to assess the competency for 1 of 1 CC (CMS 209 TP #1), and 1 of 2 TS (CMS 209 TP # 1) for their supervisory responsibilities from 08/30/2022 to 05/14/2024. 2. The laboratory could not provide competency assessment documentation for 1 of 1 CC (CMS 209 TP

	#1), 1 of 2 TS (CMS 209 TP # 1) for 2022 and 2023. 3. The laboratory failed to provide competency assessment for 1 of 1 TP who performed histopathology examinations in 2022 and 2023. 4. The AGM confirmed the findings above on 05/14 /2024 around 1:00 pm.