Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2158019	07/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology Group	822 Pine St, Lower Level, 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
D0000	A recertification certification survey was conducted by the Pennsylvania State Agency for Schweiger Dermatology Group on 07/21/2026. The laboratory was found out of compliance with the following condition: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with the Lead Lab Tech (LLT), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 2 of 2 thermometers and 1 of 1 hygrometer /thermometer used to ensure acceptable storage and operating temperatures were met in the laboratory when histopathology testing was performed from 01/27/2025 to 07/21 /2026. Findings Include: 1. On the day of the survey, 07/21/2026 at 10:45 am, observation of the laboratory revealed 1 of 1 room temperature and humidity hygrometer/thermometer with no expiration date, serial number or identifying label on the instrument. 2. Further observation revealed 2 of 2 Traceable thermometers (S/N: 240260321, 240260322) due 26 Mar 2026. 3. The laboratory could not provide maintenance/function check records for the 2 of 2 thermometers and 1 of 1 hygrometer /thermometer used to record temperature and humidity in the laboratory when histopathology testing was performed from 01/27/2025 to 07/21/2026. 3. The LLT confirmed the above findings on 07/21/2026 at 11:00 am.
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 review of the laboratory's temperature logs, lack of documentation, and interview with the Lead Lab Tech (LLT), the laboratory failed to document corrective action taken when refrigerator storage temperatures were recorded below the laboratory's acceptable range of 2 to 8 degrees Celsius (C) for Immunohistochemical (IHC) stains used when histopathology microscopic examinations were performed for 6 of 18 months from 01/27/2025 to 07/21/2026. Findings include: 1. On the day of survey, 07/21/2026 at 10:30 am, review of the laboratory's refrigerator temperature logs revealed IHC stains storage temperatures below 2 to 8 degrees C were recorded for the following 6 of 18 months from 01/27/2025 to 07/21/2026: - 10/14/2025 - 12/29/2025 - 01/23/2026 - 03/20/2026 - 04/27/2026 - 05/26/2026 2. The laboratory could not provide documentation of corrective actions taken when refrigerator temperatures were recorded out of the laboratory's acceptable range. 3. Review of the laboratory's test logs revealed 4,480 histopathology slide examinations using IHC stains from 01/27/2025 to 07/21/2026. 4. The LLT confirmed the above findings on 07/21/2026 at 11:00 am.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), personnel qualification records, and interview with the Lead Lab Tech (LLT), the laboratory failed to ensure 1 of 3 testing personnel (TP) met the minimum requirements of 493.1489 to perform high complexity testing from 01/05/2026 to 07/21/2026. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory

	technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the CLIA laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the Lead Lab Tech (LLT), the laboratory failed to ensure that 1 of 3 testing personnel (TP) met the minimum educational requirements to perform high complexity macroscopic histopathology examinations from 01/05/2026 to 07/21/2026. Findings include: 1. On the day of survey, 07/21/2026 at 09:30 am, the laboratory failed to provide documentation for the equivalency evaluation performed for education obtained from a foreign institution for 1 of 3 TP (CMS 209 TP #3 dated 07/21/2026) who performed high complexity macroscopic histopathology examinations (grossing and inking) from 01/05/2026 to 07/21/2026. 2. The laboratory reported testing volume of 15,153 Histopathology examinations from 01/05/2026 to 07/21/2026. 3. The LLT confirmed the finding above on 07/21/2026 at 10:30 am.