Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2171014	09/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Schweiger Dermatology Group	50 Monument Rd, Ste #301, Bala Cynwyd, 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 survey conducted by the Pennsylvania State Agency on 09/04/2025 found the Schweiger Dermatology Group laboratory to be out of compliance with the following condition: 493.1250 Condition: Analytic systems
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: A. Based on review of laboratory policy, temperature records, and interview with the General Manager (GM), the laboratory failed to monitor and document room temperature for 43 of 673 days to ensure substantial proof of efficacy was provided for reagents and operating conditions were met for reliable test system operation when chemistry testing was performed from 11/01/2023 to the day of survey as required per PA regulations. Findings include: 1. The PA State regulation 5.46 states: "Reagents, procedures or equipment which have been demonstrated to be inadequate for clinical laboratory use as evidenced by reliable data from generally acceptable scientific testing and evaluating sources shall be prohibited for use by clinical laboratories upon specific notification by the Department. Also, reagents, equipment and procedures which do not have substantial proof of efficacy either by trial or extended use experience shall be prohibited for routine use". 2. The laboratory's Quality Control of Laboratory Equipment policy states, "Temperature and humidity devices are maintained in laboratory and ranges are recorded daily when testing is performed." 3. On the day of survey, 09/04/2025 at 10:12 am, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document room temperatures (laboratory's acceptable range 20 C to 25 C) for 43 of 673 days to ensure proper storage of reagents and operating conditions were met for the following reagents used in the laboratory from 11/01/2023 to 09/04/2025: - Clarity Diagnostics Pregnancy

	One Step Rapid test cassettes (manufacturer's acceptable range 2C to 30 C) 4. Review of the laboratory's pregnancy test logs revealed that the laboratory performed 44 urine pregnancy tests from 11/01/2023 to 09/04/2025. 5. The GM confirmed the above findings on 09/04/25 at 11:29 am. B. Based on review of laboratory procedures, lack of documentation and interview with the General Manager (GM), the laboratory failed to follow and document quality control (QC) procedures to establish the accuracy, specificity and precision of 1 of 1 chemistry test performed from 11/01/2023 to the date of survey as required per PA regulations. Findings include: 1. The PA State regulation 5.61(b) states: "A degree of accuracy, specificity and precision satisfactory to the Department shall be shown in quality control records at all times". 2. The laboratory's Urine Pregnancy procedure states, "When opening a new box of pregnancy tests, run a control test with a known pregnant specimen and a known non-pregnant specimen, and record." 3. On the day of survey 09/04/2025, the laboratory failed to provide documentation for the positive and negative external QC performed when a new box was opened for 1 of 1 chemistry test (Urine human chorionic gonadotropin) performed from 11/01/2023 to 09/04/2025. 4. Review of the laboratory's pregnancy test logs revealed that the laboratory performed 44 urine pregnancy tests from 11/01/2023 to 09/04/2025. 5. The GM confirmed the above findings on 09/04/25 at 11:29 am.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation and interview with the General Manager (GM), the laboratory failed to ensure a positive and negative control was performed and documented each day of patient testing as required under 493.1256 when Potassium Hydroxide (KOH) microscopic examinations were performed for 16 of 16 months from 11/01/2023 to 03/05/2025. Refer to D5449
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with the General Manager (GM), the laboratory failed to ensure that 1 of 1 laboratory procedure manual in use for Histopathology was approved, signed and dated by the current Laboratory Director (LD) for 5 of 5 months from 04/01/2025 to 09/04/2025. Findings include: 1. On the day of survey 09/04/2025 at 09:49 am, review of the laboratory procedure manual in use for Histopathology revealed the laboratory failed to ensure all procedures were approved, signed and dated by the current LD when

	histopathology testing was performed for 5 of 5 months from 04/01/2025 to 09/04 /2025. 2. The laboratory performed 138 histopathology examinations in 2024 (CMS-116, estimated annual volume, dated 08/20/2025). 3. The GM confirmed the above findings on 09/04/2025 at 11:29 am.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the General Manager (GM), the laboratory failed to document a positive and negative control each day of patient testing for Potassium Hydroxide (KOH) microscopic examinations performed for 16 of 16 months from 11/01/2023 to 03/05/2025. Findings include: 1. The laboratory's KOH examination procedure states, "On the KOH log sheet, each slide must be determined to be Acceptable or Unacceptable by circling "Good" or " Poor" (Quality Control). The provider will then sign each test entry". 2. On the day of survey, 09/04 /2025 at 10:04 am, the laboratory failed to provide documentation of the positive and negative quality control performed every day of patient testing for KOH microscopic examinations performed from 11/01/2023 to 03/05/2025. 3. The laboratory performed 130 KOH microscopic examinations from 11/01/2023 to 03/05/2025. 4. The GM confirmed the above findings on 09/04/2025 at 11:29 am. *REPEAT DEFICIENCY