

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1023143	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Schweiger Dermatology, Pc - Millburn	Street Address, City, State 12 East Willow Street, Millburn, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Testing personnel (TP), the laboratory failed to have a complete procedure for Biannual Assessment (BA) on the date of survey. The findings include: 1) The BA procedure states the the reviewing pathologists for BA are Dr. Mark Jacobson and Dr. Paul CHU. 2) The BA for calendar year 2022 was not reviewed by the above mentioned pathologists. 3) The BA procedure does not include not the name and credentials of the current second and third party reviewing pathologists. 4) The TP confirmed on 2/7/23 at 12:00 pm that the laboratory did not have the aforementioned complete procedure.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Flammable Cabinet and interview with the Testing Personnel (TP), the laboratory used expired reagents for Histopatholgy testing</p>

from 1/26/23 to the date of survey. The findings include: 1. Xylene Substitute XS-3 Lot # 146548 expired 1/26/23. 2. StatLab Marking Dye Lot # 4249 expired 1/31/23. 3. Approximately 10 patients were tested with the expired reagent. 4. The TP confirmed on 2/7/23 at 12:30 pm that the laboratory used expired reagent.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Records (PR) and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the education records were available on the date of the survey. The finding includes: 1. Education records were not available for two out of three TP. 2. The TP confirmed on 2/7/23 at 1:00 pm that education records were not available.