

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2151557	(X3) Date Survey Completed 03/05/2019
Name of Provider or Supplier Schweiger Dermatology Group, Pc	Street Address, City, State 1000 Route 35,, Middletown, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Histopathology Slides (HS) and interview with the Office Manager (OM), the laboratory failed to retain HS from from July 2018 to the date of survey. The finding includes: 1. Review of ten patient records revealed that five out of the ten patient's slides were not available at the time of the survey. 2. The OM confirmed on 3/5/19 at 2:00 pm the HS were not retained.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station and interview with the Office Manager (OM), the laboratory failed to label all staining jars used for Histopathology</p>

testing from 7/25/18 to the date of the survey. The OM confirmed on 3/5/19 at 1:35 pm that the staining jars were not labeled.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of the Competency Assessment (CA) records, review of the personnel files and interview with the Office Manager (OM), the laboratory failed to evaluate and document the performance of the testing personnel from July 2018 to the date of survey. The OM confirmed on 3/5/19 at 2:30 pm that CA was not performed on TP