

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2172816	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Schweiger Dermatology Group	Street Address, City, State 701 East Baltimore Pike, Ste #B, Kennett Square, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the KOH examination policy and interview with the general manager, mohs histotechnologist and lead medical assistant, the laboratory failed to include quality control (QC) procedures in the KOH examination policy in 2020. Findings Include: 1. On the date of survey, 02/13/2020, review of the KOH examination policy revealed, QC procedures were not included in the policy "updated 2020 and approved by the laboratory director". 2. Review of KOH logs revealed, QC was not documented each day of patient testing from 01/06/2020 to 02/13/2020. 3. 6 KOH examinations were performed from 01/06/2020 to 02/13/2020. 4. The general</p>

manager, mohs histotechnologist and lead medical assistant confirmed the finding above on 02/13/2020 around 01:00 pm. *****KOH: Potassium Hydroxide

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

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.

This STANDARD is not met as evidenced by:

Based on observation of reagents and interview with the general manager, mohs histotechnologist and lead medical assistant, the laboratory failed to label davidson marking systems dye bottles (7 of 7) with open and expiration dates prior to use from 2019 to the day of survey. Findings Include: 1. On the day of survey, 02/13/2020, the histotechnologist pulled out a box of davidson marking systems dye bottles that were stored in an over head cabinet, they presented the bottles in use to the examiner. 2. Observation of the bottles revealed, the following Davidson Marking systems dye bottles (7 of 7) were not labeled with open and expiration dates prior to use: - 2 of 2 black dyes bottles - 2 of 2 blue dyes bottles - 1 of 1 red dye bottle - 1 of 1 green dye bottle - 1 of 1 yellow dye bottle 2. The general manager, mohs histotechnologist and lead medical assistant confirmed the findings above on 02/13/2020 around 1:20 pm.