

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1029392	(X3) Date Survey Completed 07/29/2020
Name of Provider or Supplier Schweiger Dermatology Group	Street Address, City, State 822 Pine Street Suite 2a, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records and interview with the office manager, the laboratory failed to retain QC records for Potassium Hydroxide (KOH), scabies and frozen section examinations analyzed from 02/28/2018 to 09/04/2018. Findings include: 1. On the day of survey, 07/29/2020, the laboratory could not to provide QC records for KOH, scabies and frozen section examinations performed from 02/28/2018 to 09/04/2018. 2. The office manager confirmed the above finding on 07/29/2020 around 12:15 am.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: A. Based on review of competency assessment records and interview with office manager, the laboratory failed to assess the competency for 4 of 5 testing personnel (TP) who performed KOH and Scabies in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 07/29/2020, review of TP competency assessment recorded reviewed, the laboratory did not document competency assessment separately for 4 of</p>

5 TP performing KOH and Scabies examinations analyzed in 2018, 2019 and 2020. 2. The office manager confirmed the above finding on 07/29/2020 around 10:15 am. B. Based on review of the laboratory policies and interview with the office manager, the laboratory failed to establish a competency assessment policy to assess the competency for 4 of 5 personnel for their regulatory responsibilities in 2018, 2019 and 2020. Findings include: 1. On the day of survey, 07/29/2020, the laboratory could not provide a competency assessment policy or documented competency assessments for 4 of 5 personnel (On the CMS 2019 Testing Personnel form, listed as a clinical consultant and as a technical supervisor) in 2018, 2019 and 2020. 2. The office manager confirmed the above finding on 07/29/2020 around 10:15 am.

D5301

TEST REQUEST
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with office manager, the laboratory failed to establish a test requisition for Potassium Hydroxide (KOH) and Scabies examinations analyzed from 02/28/2018 to the day of survey. Findings include: 1. On the day of survey, 07/29/2020, the laboratory could not to provide test requisitions for KOH and Scabies examinations analyzed from 02/28/2018 to 07/29/2020. 2. The laboratory performed the following number of tests in 2018, 2019 and 2020: - 2018 (02/28/2018 to 12/31/2018) KOH - 43 Scabies - 8 - 2019 KOH - 31 Scabies - 5 - 2020 (01/01/2020 to 07/29/2020) KOH - 14 Scabies - 2 3. The office manager confirmed the above finding on 07/29/2020 around 10:35 am

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the office manager, the laboratory failed to establish a patient test report for Potassium Hydroxide (KOH) and Scabies examinations analyzed from 02/28/2018 to the day of survey. Findings include: 1. On the day of survey, 07/29/2020, the laboratory could not to provide patient test reports for KOH and scabies examinations analyzed from 02/28/2018 to 07/29/2020. 2. The laboratory performed the following number of tests in 2018, 2019 and 2020: - 2018 (02/28/2018 to 12/31/2018) KOH - 43 Scabies - 8 - 2019 KOH - 31 Scabies - 5 - 2020 (01/01/2020 to 07/29/2020) KOH - 14 Scabies - 2 3. The office manager confirmed the above finding on 07/29/2020 around 10:37 am.