

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2158019	(X3) Date Survey Completed 12/14/2022
Name of Provider or Supplier Schweiger Dermatology Group	Street Address, City, State 822 Pine St, Lower Level, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's procedure manual, peer review records, and interview with the lead histotechnologist (HT), the laboratory failed to ensure that the verification of accuracy for microscopic examinations for histopathology were performed at least twice annually, as required for tests not included in subpart I in 2021. Findings Include: 1. On the day of the survey, 12/14/2022 at 10:55 am, the laboratory could not provide documentation that the verification of accuracy for histopathology slide examinations stained using immunohistochemicals, special stains, and hematoxylin and eosin (H&E) were performed at least twice annually in 2021. 2. The laboratory performed 17,040 histopathology examinations in 2021 (annual volume listed on form CMS-116). 3. The HT confirmed the findings above on 12/14/2022 around 12:00 pm.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p>

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's quality control (QC) staining records and an interview with the lead histotechnologist (HT), the laboratory failed to check for negative staining reactivity each time of use for 16 of 16 immunohistochemical (IHC) stains used for histopathology examinations from 01/05/2021 to the date of the survey. Findings include: 1. On the day of the survey, 12/14/2022 at 09:45 am, review of the laboratory's IHC quality control log revealed that a control for negative reactivity was not performed for each use of the following 16 of 16 IHC stains used for histopathology examinations from 01/05/2021 to 12/14/2022: -Melan A -SOX10 -CD68 -CD7 -CD8 -CD30 -KI67 -CK20 -AEI/AE3 -S100 -Factor XIIIa -CD20 -CD3 -CD34 -CD4 -CD5 2. In 2021, 1,757 IHC stained slides were used for histopathology examinations. 3. The HT confirmed the findings above on 12/14/2022 at 12:00 pm.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on the lack of quality assurance (QA) documentation and an interview with the lead histotechnologist (HT), the laboratory director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory from 01/05/2021 to the date of the survey. Findings include: 1. On the date of the survey, 12/14/2022 at 11:14 am, the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 01/05/2021 to 12/14/2022. 2. The laboratory performed 17,040 histopathology examinations in 2021 (the annual volume listed on the CMS-116 form). 3. The HT confirmed the findings above on 12/14/2022 around 12:00 pm.