

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0689176	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Dermatology Associates Lancaster Ltd	Street Address, City, State 1650 Crooked Oak Drive, Lancaster, 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
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> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the Mohs Laboratory Technologist (LT), the laboratory did not document Hematoxylin and Eosin (H & E) stain QC monitoring activities for intended reactivity and review of QC documents by the pathologist every day of patient testing from 02/10/2021 to the day of survey. Findings include: 1. On the day of survey 02/15/2023 at 09:50 a.m., the laboratory could not provide QC documentation for staining characteristics for the H&E stain performed and review of QC documents by the pathologist every day of patient testing from 02/10/2021 to 02/15/2023. 2. The LT confirmed the finding above on 02/15/2023 around 10:30 am.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory competency assessment records and interview with the Mohs Laboratory Technologist (LT), the laboratory failed to assess the competency of 1 of 2 testing personnel (TP) who performed the Mohs microscopic examinations from 02/10/2021 to the day of survey. Findings include: 1. On the day of survey, 02/15/2023 at 08:41 am, the laboratory could not provide the annual competency assessment documentation for 2021 and 2022 for TP#2 (CMS 209 TP#2) who performed the Mohs microscopic examinations. 2. The LT confirmed the finding above on 02/15/2023 around 10:30 am.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on review of the proficiency testing records and interview with the Mohs Laboratory Technologist (LT), the Technical Supervisor (TS) failed to assess test performance examination through testing previously analyzed specimens or internal blind testing samples for 1 of 1 TP (CMS 209 TP#10) performing grossing examinations from 02/10/2021 to the day of survey. Findings include: 1. On the day of survey, 02/15/2023 at 09:25 am, the laboratory could not provide the documentation to assess test performance examination through testing previously analyzed specimens or internal blind testing samples for 2021 and 2022 for TP#10 (CMS 209 TP#10) who performed the grossing examinations. 2. The LT confirmed the finding above on 02/15/2023 around 10:30 am.