

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0689176	<b>(X3) Date Survey Completed</b> 11/12/2024
<b>Name of Provider or Supplier</b> Dermatology Associates Lancaster Ltd	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, lack of documentation, and interviews with the Mohs Laboratory Technologist (LT) and laboratory director (LD), the laboratory failed to ensure a written procedure was available for microscopic histopathology slide examinations performed from 02/17/2023 to the date of the survey.. Findings Include: 1. On the date of survey, 11/12/2024, the laboratory failed to provide a written procedure for microscopic histopathology slide examinations performed from 01/17/2023 to 11/12/2024. 2. The LD and LT confirmed the finding above on 11/12/2024 at 1:00 pm</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview with the Mohs Laboratory Technologist (LT), the laboratory failed to document the internal cryostat temperature to ensure operating conditions were met for 1 of 1 Leica 1510S Cryostat used to perform MOHS micrographic slide examinations from March 2024 to September 2024. Findings include: 1. On the day of survey, 11/12/2024 at 11:00 am, review of the laboratory temperature logs revealed the laboratory failed to document the internal cryostat temperature of 1 of 1 Leica 1510S cryostat for the following days when MOHS micrographic slide examinations were performed to ensure operating conditions were met: - 03/28/2024 - 09/19/2024 2. The laboratory's Daily Routine procedure stated, "2. Check cryostat temperature and document." 3. The LT confirmed the findings above on 11/12/2024 at 11:00 am.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and interview with the Mohs Laboratory Technologist (LT), the laboratory failed to document the positive and negative control each day of patient testing for KOH and Mineral Oil (Scabies) examinations performed from January 2024 until day of survey. Findings include: 1. The laboratory Quality Control (QC) Program policy states, " Each day that this procedure is performed, a positive and a negative control sample will be analyzed in exactly the same manner as patient samples. The results obtained with control materials will be recorded on a sheet that contains the following information: name of procedure, description and source of positive control, results expected for the positive control, description and source of negative control, results expected for the negative control, date of test, an identifier such as initials indicating who performed the test, results obtained with the positive control, and results obtained with the negative control." 2. On day of survey 11/12/2024 at 9:30 am review of the laboratory's Prep logs for Scabies and KOH revealed the laboratory failed to document a positive and negative control each day of patient testing for the following days from January 2024 to the date of the survey: - 2 out of 17 days KOH examinations were performed: - 04/05 /2024 - 05/20/2024 -1 out of 17 days Mineral Oil (Scabies) examinations were performed: - 06/05/2024 3. The LT confirmed the findings above on 11/05/2024 at 9: 50 am

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(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.

This STANDARD is not met as evidenced by:  
Based on review of quality control (QC) records, lack of documentation, and interviews with the Mohs Laboratory Technologist (LT) and Laboratory Director (LD), the laboratory failed to document all control procedures performed for microscopic histopathology examinations from 02/16/2023 to 11/12/2024. Findings include: 1. On the day of survey 11/12/2024 at 11:00 am, the laboratory failed to provide documentation for positive and negative reactivity each time of use for the following 36 of 36 immunohistochemical stains (IHC) used for microscopic histopathology examinations performed from 02/2023 to 11/2024: CD3 CD4 CD8 CD20 CD30 HMB45 CD31 CD34 CD45 CD66 CD138 CEA(Monoclonal) EMA Adipophilin BerEP-4 FLI-1 P16 Smooth Muscle Actin Synaptophysin PMS-2 Melan-A Prame S-100 Sox-10 CK 5/6 CK7 CK 20 ErG Factor XIIIa Kappa Lambda MLH-1 MSH-2 MSH-6 HHV-8 PanKeratin (AE1/AE2) 2. Further review of laboratory's QC records revealed the laboratory failed to document the date and testing personnel that reviewed QC slides for IHC and special stains performed on histopathology specimens from 02/16/2023 to 11/12/2024. 3. The LT and LD confirmed the findings above on 11/12/2024 at 1:00 pm

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(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 laboratory's proficiency testing and competency records, and interview with the Mohs Laboratory Technologist (LT), the Technical Supervisor (TS) failed to evaluate assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for laboratory testing personnel (TP) who performed potassium hydroxide (KOH) and scabies examinations in 2023. Finding include: 1. On day of the survey, 11/12/2024 at 9:25 am, review of competency assessments revealed the TS failed to evaluate assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for the following TP that performed KOH and scabies examinations in 2023: - 3 of 11 TP (CMS 209 TP #4, #7, and #8) that performed Scabies examinations in 2023 - 1 of 11 TP (CMS 209 TP #3) that performed KOH examinations in 2023 2. The LT confirmed the findings above on 11/12/2024 at 10:30 am.