

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0698445	<b>(X3) Date Survey Completed</b>  01/30/2025
<b>Name of Provider or Supplier</b>  Boston University Dermatology, Inc	<b>Street Address, City, State</b>  725 Albany Street, 8th Floor, Suite B, Boston, MA	
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>D0000</b>	A CLIA recertification survey was conducted for the Boston University Dermatology, Inc. laboratory on 1/30/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
<b>D5217</b>	<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 record review and interview with the Administrative Director (AD) on 1/30/2025, the laboratory failed to verify at least twice annually procedures it performs that are not included in subpart I of this part as evidenced by the following: The surveyor reviewed the laboratory's records for twice annual peer slide review of histopathology Mohs slide examinations for calendar years 2023 and 2024. The review revealed that the laboratory failed to perform peer slide review for calendar years 2023 and 2024. The last documented peer slide review was performed on 12/16/2022. Note: The laboratory did not perform Mohs slide examinations from 5/2023 to 10/2023. The AD confirmed in an interview on 1/30/2025 at 12:27 P.M. that the twice annual peer slide review was not performed twice annually for calendar years 2023 and 2024 when Mohs slide examinations was being performed. The laboratory performs 319 Mohs cases annually. .</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Administrative Director (AD) on 1/30/2025, the laboratory failed to document the temperature of the Cryostat as evidenced by the following: The surveyor reviewed the laboratory's Cryostat temperature records for calendar years 2023 and 2024. The review revealed that the laboratory failed to document the temperature of the Cryostat each day of Mohs skin slide examinations from 10/16/2023 to 9/10/2024. The AD confirmed in an interview on 1/30/2025 at 11:18 A.M. that the temperature of the Cryostat was not being documented each day of Mohs skin slide examinations from 10/16/2023 to 9/10/2024. The laboratory performs 319 Mohs slide examinations annually. .

**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.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Administrative Director (AD) on 01/30/2025, the laboratory failed to document a control slide of known reactivity with each patient slide or group of patient slides when differential or special staining was performed as evidenced by the following: The surveyor reviewed the laboratory's Mohs histopathology quality control (QC) records for calendar years 2023 and 2024. The review revealed the laboratory failed to document the hematoxylin and eosin (H&E) stain QC each day of Mohs skin slide examinations from 10/26/2023 to 04/01/2024. The AD confirmed in an interview on 1/30/2025 at 12:10 P.M. that the H&E stain QC was not being documented each day of Mohs slide examinations from 10/26/2023 to 04/01/2024. The laboratory performs 319 Mohs slide examinations annually.  
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**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(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 record review and interview with the Administrative Director (AD) on 1/30/2025, the laboratory failed to indicate on the patient final test report the name and address of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed eight (8) patient final test reports between October 2023 and January 2025 in the Electronic Medical Record (EMR) Epic. The review revealed that the laboratory failed to indicate the name and address of the laboratory location where the test was performed for eight (8) out of eight (8) patient final test reports. The AD confirmed in an interview on 1/30/2025 at 1:47 P.M. that the patient final test reports did not indicate the name and address of the laboratory where the test was performed. The laboratory performs 319 Mohs cases annually.