

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0976301	(X3) Date Survey Completed 10/03/2024
Name of Provider or Supplier Boston Dermatology & Laser Center	Street Address, City, State 30 Lancaster Street, Boston, MA	
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
D0000	A CLIA recertification survey was conducted for the Boston Dermatology & Laser Center laboratory on 10/03/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 record review and interview with the Regional Operations Director (ROD) on 10/3/2024, 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 procedure for twice annual peer slide review of histopathology (Mohs) cases on 10/3/2024. The review revealed that laboratory's procedure for peer slide review of histopathology (Mohs) cases stated that three (3) Mohs cases would be twice annually reviewed by another dermatopathologist to verify the accuracy of the diagnoses. A review of calendar years 2022, 2023, and 2024 quality assessment records for histopathology revealed that only one peer slide review was performed in 2023. The ROD interviewed on 10/3/2024 at 11:33 A.M. verified that the twice annual peer slide review was not performed twice annually for calendar year 2023. The laboratory performs 400 Mohs cases annually. This is a repeat deficiency. .</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Regional Operations Director (ROD) on 10/3/2024, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236 as evidenced by the following: The surveyor reviewed the laboratory's procedure for twice annual peer slide review of histopathology (Mohs) cases on 10/3/2024. The review revealed that laboratory's procedure for peer slide review of histopathology (Mohs) cases stated that three (3) Mohs cases would be twice annually reviewed by another dermatopathologist to verify the accuracy of the diagnoses. A review of calendar years 2022, 2023, and 2024 quality assessment records for histopathology revealed that only two Mohs cases were reviewed for the 12/20/2022 and 6/25/2024 slide reviews performed. The ROD interviewed on 10/3/2024 at 11:38 A.M. verified that only two Mohs cases were reviewed for each of the 12/20/2022 and 6/25/2024 slide reviews performed. The laboratory performs 400 Mohs cases annually.