

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0976301	(X3) Date Survey Completed 03/09/2020
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 and Laser Center laboratory 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 on 3/9/2020, 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: 1. The surveyor reviewed the laboratory's procedure for twice annual peer slide review of histopathology (Mohs) cases on 3/9/2020. The review revealed that laboratory's procedure for peer slide review of histopathology (Mohs) cases stated that five (5) cases would be twice annually reviewed by another dermatopathologist to verify the accuracy of the diagnoses. A review of calendar years 2018 and 2019 quality assessment records for histopathology revealed that there was no documentation available to verify that the laboratory performed twice annual peer slide reviews for histopathology (Mohs) cases for calendar years 2018 and 2019. The last documented review was performed on 12/9/17. 2. The surveyor reviewed the laboratory's procedure for twice annual KOH/Wet Prep review on 3/9/2020. The review revealed that laboratory's procedure for KOH/Wet Prep review stated that two physicians would peer review each other for accuracy of testing twice annually. A review of calendar years 2018 and 2019 quality assessment records for KOH/Wet Prep revealed that the peer review was performed only once annually for each calendar year 2018 and 2019 on 5/7/18 and 2/6/19. The Clinical Services Program Administrator interviewed on 3/9/2020 at 11:10 A.M. verified that the twice annual peer slide review was not performed for calendar years</p>

2018 and 2019 and that twice annual KOH/Wet Prep review was performed once only for each calendar year 2018 and 2019. The laboratory performs 200 Mohs cases and 100 KOH/Wet Preps 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. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on record review and interview on 3/9/2020, 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 Mohs histopathology quality control (QC) records on 3/9/2020 for calendar years 2018 and 2019. The review revealed that the laboratory failed to document the hematoxylin and eosin (H&E) stain QC on four (4) days of testing, 10/9/19, 10/16/19, 10/17/19, and 10/23/19. The Clinical Services Program Administrator confirmed in an interview on 3/9/2020 at 10:38 A.M. that the H&E stain QC was not documented for four (4) days in 2019. Twenty-four (24) Mohs surgeries were performed between 10/9/19 and 10/23/19. .