Boston Bio Lab, Inc

1395 Brickell Avenue, # 800, Miami Florida 33131

May 28, 2020

FDA Submission # EUA201263

Dear Sir or Madam,

Please be advised that Boston Bio Lab, Inc has submitted an application and Assay Study to the U.S. Food and Drug Administration (FDA) on May 20th, 2020. The submittal to the FDA was for the Serological Testing for COVID-19 test kits that identify IgM and IgG antibodies in the blood, plasma, and or serum.

Attached to this letter is the assay study that was submitted to the FDA (proprietary information redacted) and the Acknowledgment letter from the U.S. Food and Drug Administration dated May 20, 2020.

If I may be of any further assistance, I can be reached at the number listed below or directly at 1(305) 992-5519.

Sincerely,

Dr. Richard Levin
CMO, Boston Bio Lab

1348 E Hillsboro Blvd, # B
Deerfield Beach, FL 33441
www.bostonbiolab.com
561-631-2143

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

5/20/2020

Richard Levin
Boston Bio Lab, Inc.
1395 Brickell Avenue, Suite 800
Miami, FL 33131
UNITED STATES

Dear Richard Levin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA201263
Received: 5/20/2020
Applicant: Boston Bio Lab, Inc.
Device: Boston Bio EZ COVID-19

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov