Acknowledgment Letter

8/27/2020

Sonia Lecce, MBA, Sr. Regulatory Consultant
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UNITED STATES

Dear Sonia Lecce, MBA:

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 contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA202623
Received: 8/27/2020
Applicant: Freedom For All Diagnostics™, Inc.
Device: SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

We will notify you when the review of this document has been completed or if any additional information is required. 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