



Acknowledgment Letter

10/1/2021

Donald Henton
Vela Diagnostics USA, Inc.
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Fairfield, NJ 07004
UNITED STATES

Dear Donald Henton:

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 address listed below. 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: EUA201918/S003
Received: 10/1/2021
Applicant: Vela Diagnostics USA, Inc.
Device: ViroKey SARS-CoV-2 RT-PCR Test 2.0 (4x48)

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