June 12, 2023

Boon King Teh
Head of Quality Assurance and Regulatory Affairs
Vela Diagnostics USA, Inc. on behalf of Vela Operations Singapore Pte. Ltd.
353C US Route 46 West, Suite 250
Fairfield, NJ 07004

Re: EUA201918/S001 and EUA201918/S003
Trade/Device Name: ViroKey SARS-CoV-2 RT-PCR Test v2.0
Dated: October 31, 2020 and October 1, 2021
Received: November 2, 2020 and October 1, 2021

Dear Dr. Teh:

This is to notify you that your request to update the authorized labeling of the ViroKey SARS-CoV-2 RT-PCR Test v2.0 to; (1) update *in silico* inclusivity analysis to fulfill Condition O. of the September 22, 2020, letter of authorization, (2) update the positive control cut-offs based on additional manufacturing data collected on observed Ct values, (3) add the KingFisher Flex instrumentation platform for use with the ViroKey SX Virus Total Nucleic Acid Kit (4x48) extraction kit, (4) add the ViroKey HT Virus Total Nucleic Acid Kit (4x96) as a new extraction method, (5) add the Hamilton Microlab STAR liquid handling system for use with the ViroKey HT Virus Total Nucleic Acid Kit (4x96) extraction kit, (6) provide control and target analyte cutoffs for the workflows using the new extraction method, (7) add instructions as well as performance data to support the use of the KingFisher Flex instrumentation platform, Hamilton Microlab STAR liquid handling system, and the ViroKey HT Virus Total Nucleic Acid Kit (4x96) extraction kit, (8) provide minor edits to the Instructions for Use and the Package Insert for clarity, is granted. Upon review, we concur that the data and information submitted in EUA201918/S001 and EUA201918/S003 supports the requested updates for use with the ViroKey SARS-CoV-2 RT-PCR Test v2. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the ViroKey SARS-CoV-2 RT-PCR Test v2.0 issued on September 22, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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