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September 30, 2021

Food and Drug Administration
Center for Devices and Radiological Health
Through email
CDRH-EUA-Templates@FDA.HHS.GOV

Re: EUA201918/A001 Amendment for ViroKey™ HT SARS-CoV-2 RT-PCR Test: additional instrument use, master mix sourcing, and packaging changes for high throughput volumes

Dear CDRH-EUA-Templates@FDA.HHS.GOV:

On behalf of Vela Operations Singapore Pte. Ltd. (Vela) we are submitting this amendment to Vela's EUA201918 ViroKey SARS-CoV-2 RT-PCR Test v2.0 has completed the validation for modifications associated with the following: (1) increased packaging volumes, (2) change in master mix sourcing, and (3) adding the ability of the PCR test to be used on a new instrumentation platform, Hamilton Microlab STAR liquid handling system (model number 173027) manufactured by Hamilton Company. The PCR test will be identified by a new name ViroKey HT SARS-CoV-2 RT-PCR Test under Vela catalog number 301085 for customers who will be using the Vela PCR test on the Hamilton Instrument in their laboratory. Vela is moving forward per the policy outlined in the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, May 2020, under section C number 4 to implement these modifications.

Contains the following files:

0001_ViroKey_HT_SARS-CoV-2_RT-PCR_Test_EUA_Amendment.zip
Within above zip file:
0010_FDA3514_09-06-2017_Secured ViroKey_HT_210930.pdf
0011_Cover Letter Vela Diagnostic EUA201918 Amendment ViroKey HT SARS-CoV-2 RT-PCR Test 210930.pdf
0012_EUA_Template_Amendment_Vela Diagnostics ViroKey HT SARS-CoV-2 RT-PCR Test 210930.pdf
0013_PL-1157 Rev1 - Test Protocol for Analytical Reactivity and Cross-reactivity Study for ViroKeyTM HT SARS-CoV-2 RT-PCR Test.pdf
0014_RT-1277 Rev 2 - Test Report for Analytical Reactivity and Cross-reactivity Study of ViroKey HT SARS-CoV-2 RT-PCR Test.pdf
0015_PL-1158 Rev 1 - Test Protocol for Interference Study on ViroKey HT SARS-CoV-2 RT-PCR Test.pdf

0016_RT-1278 Rev 1 - Test Report for Interference Study on ViroKey HT SARS-CoV-2 RT-PCR Test.pdf
0017_PL-1154 Rev 1 - Test Protocol for Analytical Sensitivity (LoD) Study for ViroKeyTM HT SARS-CoV-2 RT-PCR Test
0018_RT-1274 Rev 2 - Test Report for Analytical Sensitivity Study (LoD) of ViroKeyTM HT SARS-CoV-2 RT-PCR Test.pdf
0019_PL-1162 Rev 1 - Test Protocol for Clinical Sensitivity and Specificity with Patient Samples for ViroKey HT SARS-CoV-2 RT-PCR Test.pdf
0020_RT-1282 Rev 1 - Test Report for Clinical Sensitivity and Specificity with Patient Samples for ViroKey HT SARS-CoV-2 RT-PCR Test.pdf
0021_ViroKey HT SARS-CoV-2 RT-PCR Test patients factsheet.pdf
0022_ViroKey HT SARS-CoV-2 RT-PCR Test EUA-Vela-VirokeyHT-hcp.pdf
0023_PS104065A ViroKey SARS-CoV-2 RT-PCR Test (EUA) Product Insert v1.0 (EN).pdf
0027_Misc_Files.pdf
0025_ViroKey HT SARS-CoV-2 RT-PCR Test Box and Tube Labels – Label-183.pdf
0026_ViroKey HT Virus Total Nucleic Acid Kit Box and Tube Labels – Label-185.pdf
0027_Misc_Files.zip

If you should have any questions related to the content of this submission, please contact me directly at 973-369-3578 or via email donald.henton@veladx.com. Alternatively, please contact Penny Houston at 973-436-2631 or via email at penny.houston@veladx.com.

Sincerely,

Donald Henton
Sr. Dir. Regulatory Affairs North America
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Fairfield, NJ 07004

attachments