REALTIME LABORATORIES INC.
Cutting edge. Breaking barriers.

April 3, 2020

Re: Emergency Use Authorization (EUA) of TaqPath TM COVID-19 Combo Kit from Thermo-Fisher Scientific, Inc.

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN (Chemical, biological, radiological and nuclear defense) threats by facilitating the availability and use of MCMs (Medical Counter Measures) needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Over the past years, a number of EUA's have been issued by the FDA. A list of Current EUA's are provided in table form on the FDA's website with a list of test kit manufacturers and commercial Laboratories who use various methods for the Covid-19 testing:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

As further explained on the FDA website (above):

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19.

CDC has granted a right of reference to the performance data contained in CDC's EUA request (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

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On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to this public health emergency. The templates for these EUA submissions are available:

- "Accelerated" Template for Laboratories Certified to Perform High-Complexity Testing Under CLIA: EUA Template (updated March 6, 2020)
- Test Kit Manufacturer: EUA Template (updated March 12, 2020)

If you need additional information, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2.

Please note: A determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020, does not enable FDA to issue Emergency Use Authorizations. A separate determination and declaration are needed under section 564 of the Federal Food, Drug, and Cosmetic Act to enable FDA to issue Emergency Use Authorizations, provided other statutory criteria are met.

The FDA website further sites letters given to each manufacturer giving those manufacturers clearance to use their platforms in the SARS-CoV 19 testing measures.

RealTime Laboratories, Inc. is a CLIA and College of American Pathology (CAP) accredited laboratory which gives the lab authority to conduct tests which are high complexity in status. CoVid-19 testing is deemed a "high-complexity test" by CLIA. RealTime Laboratories, Inc. will conduct tests on the platforms manufactured by Thermo Fisher Scientific, Inc. and will only use reagents of Use for the TaqPath COVID-19 ComboKit. Two letters were given to ThermoFisher Scientific Inc., Regulatory Affairs Manager, Faith Du, on March 13, 2020, and March 24, 2020, giving authority for Thermo Fisher to release their product(s) to high complexity CLIA laboratories such as RealTime Laboratories:

https://www.fda.gov/media/136113/download

https://www.fda.gov/media/136413/download

In Summary: Because RealTime Laboratories, Inc.(RTL) is a high complexity laboratory that is both CLIA and CAP accredited and because RTL will only use the EUA approved platform from Thermo Fisher Scientific, Inc., and because RTL will only use the EUA approved TaqPath COVID 10 ComboKit as manufactured kit, RTL can and will accept specimens for determination of the presence of SARS-CoV-2. Furthermore, RTL will accept specimens submitted as nasopharyngeal swabs, nasal swabs, and sputum specimens (all of which have been validated by RTL's Validation standards).

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Respectfully submitted,

04/03/2020

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