CFX96 Touch, CFX384 Touch, CFX Opus 96, and CFX Opus 384 Real-Time PCR Systems

Instrument Operation Manual Addendum

For emergency use with the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit

The Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit is authorized for use under the US Food and Drug Administration (FDA) Emergency Use Authorization (EUA) with the CFX96 Touch, CFX384 Touch, CFX Opus 96, CFX Opus 384, CFX96 Dx, Applied Biosystems 7500 Fast Real-Time PCR Systems to qualitatively detect RNA from SARS-CoV-2 in upper respiratory tract specimens from individuals suspected of having COVID-19 by their healthcare provider. Refer to the Reliance SARS-CoV-2 RT-PCR Assay Kit instruction for use for additional information (www.bio-rad/SARS-CoV-2-RTPCR-IVD).

This instrument operation manual addendum applies to the Bio-Rad instruments listed in Table 1 that are authorized for use with the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit.

Table 1: Bio-Rad instruments Authorized for Emergency Use Only with the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit

Catalog Number	Product Name
1855485	CFX384 Touch Real-Time PCR Detection System
1855195	CFX96 Touch Real-Time PCR Detection System
12011319	CFX Opus 96 Real-Time PCR System
12011452	CFX Opus 384 Real-Time PCR System

Warnings:

- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.