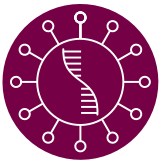




Bio-Rad SARS-CoV-2 ddPCR Kit



The Bio-Rad SARS-CoV-2 ddPCR Kit is a powerful diagnostic tool in the battle against COVID-19, with sensitivity and precision beyond that of quantitative PCR (qPCR) assays.

The SARS-CoV-2 ddPCR Kit is a partition-based endpoint reverse transcription PCR (RT-PCR) test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal anterior nasal and midturbinate nasal swab specimens, as well as nasopharyngeal wash/aspirate and nasal aspirate specimens from patients suspected of having COVID-19 by their healthcare provider.

The SARS-CoV-2 ddPCR Kit contains the 2019-nCoV CDC ddPCR Triplex Probe Assay, One-Step RT-ddPCR Supermix, and SARS-CoV-2 positive and negative standards. The kit is optimized for use on the Bio-Rad QX200 AutoDG or QXDx AutoDG Droplet Digital PCR (ddPCR) System.

The Bio-Rad SARS-CoV-2 ddPCR Kit is intended for use by qualified clinical laboratory personnel specifically trained and instructed in ddPCR techniques and in vitro diagnostic procedures.

The United States Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the Bio-Rad SARS-CoV-2 ddPCR Kit in the U.S. on May 1, 2020.

Visit [bio-rad.com/COVID-19-ddPCR](https://www.bio-rad.com/COVID-19-ddPCR) for more information.



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Features and Benefits

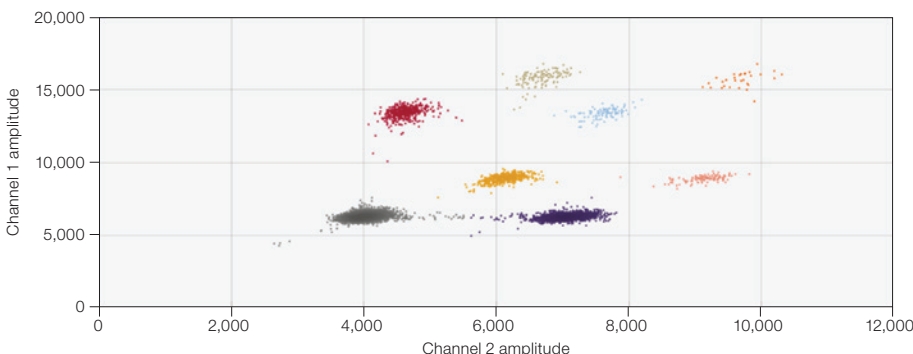
- High sensitivity and precision in low viral load
- Resistant to inhibition often seen in RT-PCR testing
- Single-well test with 3 sequences aligned to the Centers for Disease Control and Prevention (CDC) markers: SARS-CoV-2 N1 and N2 genes and the human RP gene
- Easy-to-use software and systems

Limit of Detection

Target	SARS-CoV-2 N1	SARS-CoV-2 N2
RNA concentration, copies/reaction	5.2	5.8

Limit of detection of the Bio-Rad SARS-CoV-2 Kit. Samples were extracted with Thermo Fisher Scientific's MagMAX Viral/Pathogen Nucleic Acid Isolation Kit. The limit of detection of the QIAGEN QIAamp Viral RNA Mini Kit is available in the instruction manual.

Performance Data for Bio-Rad SARS-CoV-2 ddPCR Kit



Radial multiplexing of three targets (SARS-CoV-2 N1, SARS-CoV-2 N2, and human RNase P genes). 2-D fluorescence amplitude plot shows radial multiplexing of SARS-CoV-2 N1 (N1), SARS-CoV-2 N2 (N2), and human RNase P (RP) genes using channel 1 (FAM) and channel 2 (HEX) of one of the equivalent ddPCR Systems. N1 is detected by a FAM probe, N2 by a 50% FAM and 50% HEX probe, and RP by a HEX probe. A cluster in gray (■) is triple-negative for the three targets, single-positive for N1 (■), single-positive for N2 (■), single-positive for RP (■), double-positive for N1 and N2 (■), double-positive for N1 and RP (■), double-positive for N2 and RP (■), and triple-positive for the three targets (■).

Ordering Information

Catalog #	Description
12013743	Bio-Rad SARS-CoV-2 ddPCR Kit , 2019-nCoV CDC ddPCR Triplex Probe Assay, One-Step RT-ddPCR Supermix, Exact Diagnostic SARS-CoV-2 Positive Standard, Exact Diagnostic SARS-CoV-2 Negative Standard

ddPCR Instruments and Software**	Status
17002229 QXDx AutoDG Droplet Digital PCR System , IVD system includes QX200 Droplet Reader, IVD (12001045) and Automated Droplet Generator, IVD (12001630)	CE-marked IVD system
17005351 QXDx AutoDG Droplet Digital PCR System , includes QXDx Droplet Reader (12008020) and QXDx Automated Droplet Generator (12008019)	FDA-cleared system under K181661
1864100 QX200 AutoDG Droplet Digital PCR System , includes QX200 Droplet Reader (1864003) and Automated Droplet Generator (1864101)	RUO system
1851197 C1000 Touch Thermal Cycler with 96-Deep Well Reaction Module	RUO lab equipment
1852197 S1000 Thermal Cycler with 96-Deep Well Reaction Module	RUO lab equipment
1814000 PX1 PCR Plate Sealer	RUO lab equipment

RUO, research use only.

* All systems use the following software: QuantaSoft 1.7 (10026368) and QuantaSoft Analysis Pro 1.0.

** Required to run the Bio-Rad SARS-CoV-2 ddPCR Kit. For consumables, refer to the instruction manual.

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