



## Cov2Quant™ SARS-Cov-2 Quantification kit

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One-step RT-QPCR kit

CQ-100 100 tests/kit

STORE AT -20 °C or below

Shelf life is 12 months after manufacturing



*For ABI7500/7500 Fast/Roche LightCycler® 96/Mic qPCR Cycler, 4-Channel*

### INTENDED USE

Cov2Quant™ SARS-Cov-2 Quantification kit is a One-step reverse transcription real-time PCR (RT-QPCR) kit designed to detect the novel corona virus, SARS-Cov-2, quantitatively by using reverse transcription reaction and quantitative real-time polymerase chain reaction.

### KIT COMPONENT

Cov2Quant™ SARS-Cov-2 Quantification kit		100 tests/kit
Yellow	qPCR 1-Step MIX	1,000 µl
Purple	RTase	100 µl
Green	Probe Mixture	410 µl
Blue	Negative Control	100 µl
Red	Positive Control	100 µl

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### PREREQUISITE

- Applied Biosystems 7500/7500 Fast, Roche LightCycler® 96 or Mic qPCR Cycler, 4-Channel real-time PCR instrument
- Vortex mixer
- Centrifuge with rotor for microtiter plates
- Pipettes and pipette tips with aerosol barrier
- Disposable powder-free gloves

### PRECAUTION AND WARNING

- The kit is designed for research use only (RUO) or in vitro diagnostics (IVD)
- Performing tests has to be done by well-trained and qualified personnel
- Dispose unused reagents and waste according to local regulations
- Do not modify the sample/reagent volume
- Do not mix reagent from different kits or different batches of this kit
- Avoid unnecessary freezing and thawing of the reagents



## **Cov2Quant™ SARS-Cov-2 Quantification kit**

### **PROTOCOL**

#### **A) Sample**

This kit is designed to detect Sars-Cov-2 viral RNA from total RNA extracted from human respiratory specimen such as naso/pharyngeal swab, sputum, alveolar lavage, using different sampling and RNA purification protocols. Preferred validated IVD kit for sampling: Virus Transport medium with flocked swab – cat no: ATM-1 (Avidin).

#### **B) RNA Extraction**

Commercial RNA purification kit, such as AviRNA Viral RNA Extraction Kit (AVE-100, Avidin) is recommended.

#### **C) Reagent Preparation**

Before use all components need to be thawed, gently mixed and centrifuged briefly to collect reagent solution at the bottom.

1. Mix 10  $\mu$ l qPCR 1-Step MIX, 1  $\mu$ l RTase and 4  $\mu$ l of Probe Mixture to prepare master mix per each reaction. Prepare app. 10% more volume of master mix for all the reactions to prevent pipetting error
2. Pipette 15  $\mu$ l master mix into PCR tube or 96-well PCR plate
3. Add 5  $\mu$ l of extracted RNA sample into PCR tube or 96-well PCR plate, then mix all components by pipetting. Proceed the same step with Negative Control and Positive Control
4. Close the tube with the cap or seal the 96-well PCR plate
5. Centrifuge the tubes or 96-well PCR plate to collect reagent mix at the bottom
6. Transfer the tubes or 96-well PCR plate into the real-time PCR instrument

#### **D) Real-time PCR Setting**

This kit is validated on ABI7500/ Roche LightCycler® 96/ Mic qPCR Cycler, 4-Channel real-time PCR instruments.

1. Set on the dedicated real-time PCR software for thermal cycling parameters according to the manual.
2. Set the following PCR program and fluorescence parameters, then click the start „RUN” button.



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### Real-time PCR Profile

	Cycle	Temp.	Time
Section 1	1 cycle	50 °C	10 min
	1 cycle	95 °C	2 min
Section 2	45 cycles	95 °C	10 sec
		60 °C*	30 sec

\* Select „Collect Data”

### FLUORESCENCE SETTING

Target	Fluorophore
RdRp gene	FAM
N gene	JOE/HEX
IC	Cy5
Reference dye	ROX

#### A) Analysis Setting

The values of fluorescence emitted by the specific probes and by the specific internal control probe during amplification reactions should be analyzed by the instrument software.

#### B) Result Interpretation

RdRp	N	IC	Assay Result
<42	<42	<35	COVID-19 Positive
<42	U.D	<35	Repeat the test : COVID-19 positive if RdRp<42
U.D	<42	<35	Repeat the test : COVID-19 positive if N<42
U.D	U.D	<35	COVID-19 Negative
U.D	U.D	U.D	Invalid (re-test)

\* U.D, Undetermined



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### Quality Control

Positive Control and Negative Control Ct range should be the following:

FAM	JOE/HEX	CY5	Assay Result
<33	<33	<33	Positive Control
U.D	U.D	U.D	Negative Control

## PERFORMANCE

Criteria	Result
Analytical Specificity	12 viral RNA/DNA samples were tested on the Cov2Quant™ SARS-Cov-2 Quantification kit to evaluate possible cross-reactivity. 12 viral RNA/DNA samples with no relation to the detection target of the kit were NEGATIVE - Cross reactivity: 100% Specificity
Analytical Sensitivity	Serial dilution (20,000; 2,000; 200; 20; 2 copies/test) of Sars-Cov-2 RNA (2 batches, 12 repeat) were tested. Analytical Sensitivity: 1) RdRp gene 20 copies/test; 2) N gene 20 copies/test
Repeatability	Repeatability was confirmed with identical standard samples at different time points with different Lot and testers. Criteria of repeatability was CV < 10% of Ct Value
Freeze/Thaw Safety	Freeze/Thaw Safety was confirmed by 10 times of Freeze/Thaw repeat test. Criteria of repeatability was CV < 10% of Ct Value

#### MANUFACTURER:

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#### DISTRIBUTOR:

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Made in Hungary, EU

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