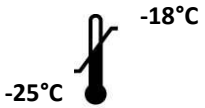
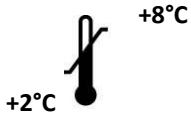
Storage



Usage



IVD

Disposal:

According to the local, regional or governmental regulations

Quality control:

Internal Control in the test
1 positive control per run
1 negative control per run

Cross reactions:

None found

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Version: 01.3

COVID-19 *direct* RT-PCR

Brief Instructions for Use

Test for the direct qualitative detection of SARS-CoV-2 on a qPCR cycler

Intended use

The COVID-19 *direct* RT-PCR is an *in vitro* real-time test based on the reverse transcriptase polymerase chain reaction (RT-qPCR) for the qualitative detection of nucleic acid from SARS-CoV-2 in samples of the upper and lower respiratory tract collected from suspected COVID-19 individuals by their healthcare provider. Positive results are an indication of the presence of SARS-CoV-2 RNA; clinical correlation with medical records and other diagnostic information is necessary to determine the patient's infection status.

Package contents:
Vials with solution A (1.6 mL) and solution B (18 µL), each for one microtiter plate (96 well), positive control PC (13 µL, optional), negative control NC (13 µL, optional), instructions for use.


All samples of biological origin and used plates / swabs are to be treated as potential carriers of infectious diseases.

When working with chemicals or when handling samples of biological origin, the safety precautions of the laboratory must be observed.

Before performing this test, read the instructions for use to familiarise yourself with the testing procedure. You can find them on www.frizbiochem.de/labdirectintro.html.

If you have any questions or problems, please contact service at FRIZ Biochem GmbH (http://frizbiochem.de/contact.html).

Test procedure

The starting material for the COVID-19 *direct* RT-PCR test is 10 µL of a solubilized patient sample per reaction. The patient sample can be obtained from sputum or smear.

	Procedure
0	Thaw all reagents completely and keep them cool (+2 °C to +8 °C) before starting the test. One Positive and one Negative Control should be included in each qPCR run.
1	Prepare the reaction solution: add 15 µL of solution B to the vial of solution A; mix/shake briefly and centrifuge if necessary. Do not vortex!
2	Pipette 15 µL of the reaction solution into each of the PCR reaction tubes/wells of the microtiter plate.
3	Add 10 µL of a solubilised patient sample or Positive Control or Negative Control per well.
4	Close the microtiter plate with an adhesive optical film or the reaction tubes with the lids provided.
5	Briefly centrifuge the microtiter plates or reaction vessels, if necessary.
6	Place the filled plate/reaction tubes in the qPCR cycler.

Settings of the qPCR / detection channels

Reverse transcription	**55°C**	**10 min**
Denaturation	**95°C**	**2 min**
Amplification	**45 cycles**	
Denaturation	**95°C**	**5 sec**
Amplification/elongation	**65°C**	**15 sec**

	SARS-general (E-gene)	SARS- CoV-2 (N-gene)	Internal Control
Reporter dye	CalFluor Red 610 -Probe	FAM-Probe	HEX-Probe
Colour	red	green	yellow
Emission	610 nm	510 nm	580 nm
Quencher	Black Hole Quencher	Black Hole Quencher	Black Hole Quencher

Interpretation of COVID-19 *direct* RT-PCR test results

SARS general (E-gene, Red 610)	SARS-CoV-2 (N-gene, FAM)	Internal control (IC, HEX)	Interpretation
Positive	Positive	Positive/ Negative	**Positive!** SARS coronaviruses detected in the examined material; confirmation for SARS-CoV-2
Positive	Negative	Positive/ Negative	**Potentially positive!** SARS corona virus detected in the examined material; no confirmation for SARS-CoV-2; re-analysis of sample if necessary.
Negative	Negative	Positive	**Negative!** No SARS coronavirus and no SARS-CoV-2 were found in the examined material.
Negative	Positive	Positive/ Negative	**Potentially positive!** No SARS coronavirus detected in the material examined, but SARS-CoV-2; re-analysis of sample if necessary.
Negative	Negative	Negative	**Invalid!** The test result cannot be evaluated.

The results are used to identify SARS-CoV-2 RNA. The SARS-CoV-2-RNA is generally detectable in respiratory samples during the acute phase of the infection. Positive results are an indication of the presence of SARS-CoV-2 RNA.

A negative result does not rule out the presence of SARS-CoV-2 RNA, as the results depend on correct sampling and a sufficient amount of RNA to be detected.