



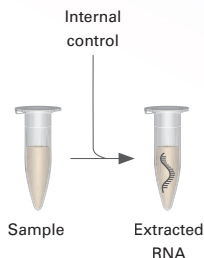
EURORealTime SARS-CoV-2

Specific direct detection of SARS-CoV-2 using real-time PCR

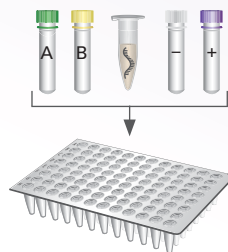
- Quick pathogen detection by means of reverse transcription and real-time PCR in one step
- High sensitivity due to simultaneous detection of two target sequences in the ORF1ab and N genes of the SARS-CoV-2 genome
- Only one reaction per sample

EURORealTime SARS-CoV-2 (order number: MP 2606-0###)

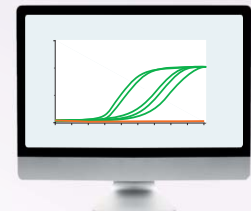
1. RNA isolation



2. Real-time PCR



3. Analysis and final report



Sample material: throat swab

The **PCR mixes** contain all the required components for reverse transcription and real-time PCR.

Compatible real-time PCR cyclers: e.g. LightCycler® 480 (Roche), 7500 Fast Real-Time PCR Instrument (Applied Biosystems), CFX 96 Touch (Bio-Rad)*

* Other devices should be validated individually by the user.

Analytical performance data

- Lower limit of detection (LoD): one SARS-CoV-2 RNA copy per μl eluate (1 cp/ μl)
- No cross reactivity was determined for nucleic acids of the following pathogens that are found in the respiratory tract or are closely related to SARS-CoV-2:

Viruses		Bacteria / Fungi	
Adenovirus 5	Coronavirus 229E	Bordetella pertussis	Streptococcus pneumoniae
Coronavirus HKU1	Enterovirus 71	Chlamydia pneumoniae	Streptococcus pyogenes
Coronavirus MERS	Influenza virus A and B	Haemophilus influenzae	
Coronavirus NL63	Parainfluenza virus 1 – 4	Legionella pneumophila	Pneumocystis jirovecii
Coronavirus OC43	Respiratory syncytial virus A and B	Mycobacterium tuberculosis	
Coronavirus SARS HKU39849	Rhinovirus	Mycoplasma pneumoniae	

Evaluation

In an evaluation study, the diagnostic sensitivity and specificity of the EURORealTime SARS-CoV-2 were investigated in comparison to a SARS-CoV-2 real time PCR reference test. The correlation of positive and negative results obtained with the two test systems in the analysis of 164 throat swabs was 98.2% and 100%, respectively.

164 samples (throat swabs)	External precharacterisation using a SARS-CoV-2 real-time PCR reference test**	
	positive	negative
EURORealTime SARS-CoV-2	positive: 107	negative: 0
	negative: 2	55

** Test kit from TIB MOLBIOL