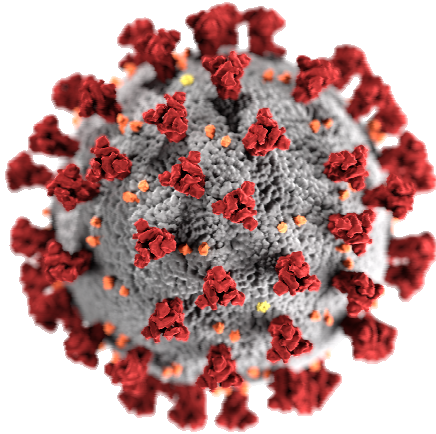


## SARS-CoV-2 Real Time PCR LAB-KIT™



The genetic test SARS-CoV-2 Real Time PCR LAB-KIT™ is designed for the specific identification and differentiation of 2019 Novel Coronavirus (SARS-CoV-2) in respiratory samples from patients with signs and symptoms of COVID-19 infection. Virus identification is based on the conserved **Orf1ab** and **N** gene region for SARS-CoV-2.

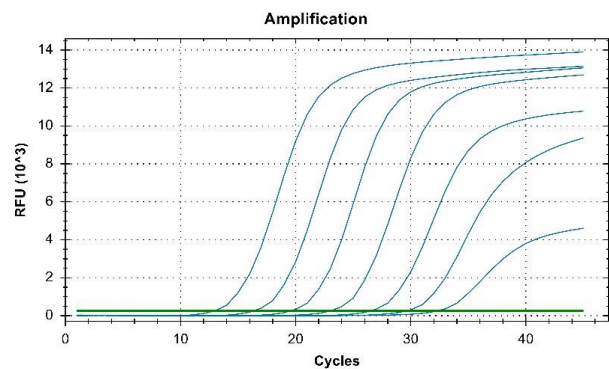
The test meets the requirements of the WHO Recommendation "Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases. Interim guidance. March 2, 2020.

- Validated and registered in URPL
  - Samples from upper respiratory tract specimens: sputum, endotracheal aspirate, or bronchoalveolar lavage, a nasopharyngeal aspirate or combined nasopharyngeal and oropharyngeal swabs. Other clinical specimens as blood, urine and stool
  - Approved for use in diagnostics - **CE and IVD**
  - Identification of two genes: **Orf1ab** and **N**
  - Lyophilized reagents
  - For use in open PCR systems
  - **All-in-One**: the lyophilized PCR reaction mixture contains all components. Add only RNA virus.
  - Use as many PCR microtubes as you need.
  - Test sensitivity  $\geq 10$  RNA copies
  - Storage and transport in the field from **+2 to +40°C**
  - The hydrated positive control is stable for 6 defrost / freeze cycles
  - **Test time = 62 min** PCR amplification
  - Expiry date: min. 2 years
  - No cross-reactivity to microorganisms and respiratory viruses
- Sensitivity: > 99%, Specificity: > 99%**

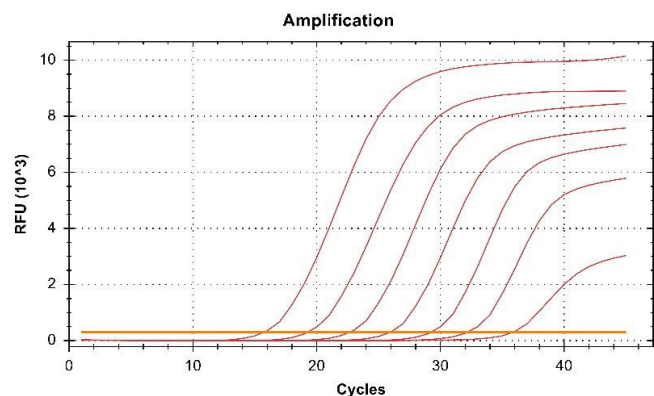
### Kit components:

SARS-CoV-2 8-well strips  
 Rehydration Buffer  
 SARS-CoV-2 Positive Control  
 Negative control  
 Water RNase/DNase free  
 Tear-off 8-cap strips

RT-PCR result for a series of dilutions of the **Orf1ab** gene copy (from the left  $10^7 - 10^1$  copies of the gene)



RT-PCR result for a series of dilutions of the **N** gene copy (from the left  $10^7 - 10^1$  copies of the gene)



### Packaging:

8 - well strips - 96 tests – catalog number: PCR 5008  
 96-well plate – catalog number: PCR 5096

**PERFORMANCE DIAGRAM**

**Sample:**  
sputum, endotracheal aspirate, bronchoalveolar lavage, a nasopharyngeal aspirate, nasopharyngeal and oropharyngeal swabs, blood, urine and stool

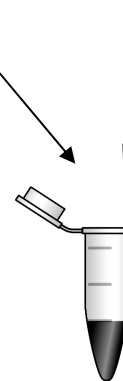
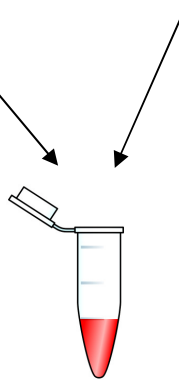
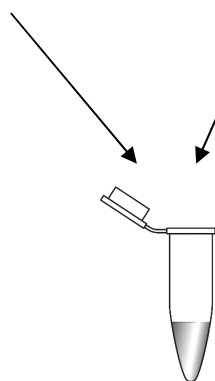
*Isolation of virus genetic material*

**RNA SARS-CoV-2**

15  $\mu$ L Rehydration Buffer  
+ 5  $\mu$ L Negative control

15  $\mu$ L Rehydration Buffer  
+ 5  $\mu$ L RNA SARS-CoV-2

15  $\mu$ L Rehydration Buffer  
+ 5  $\mu$ L Positive control



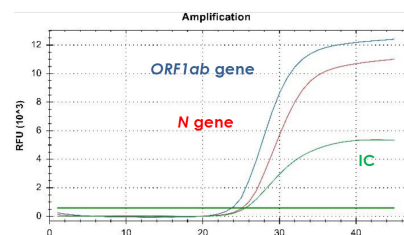
Each PCR microtube contains a lyophilized reaction mixture

**Negative control**

**Examined sample**

**Positive control**

Close all PCR microtubes tightly and place in thermocycler



Analysis of obtained data  
Output of result