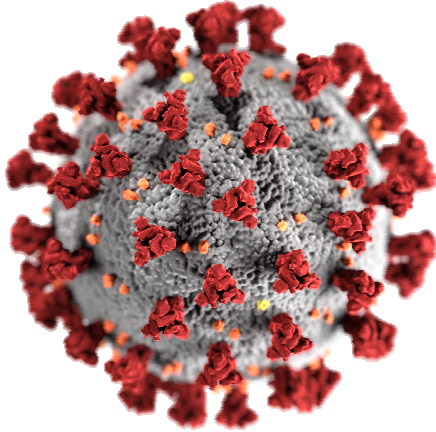


SARS-CoV-2 Real Time PCR LAB-KIT™



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.

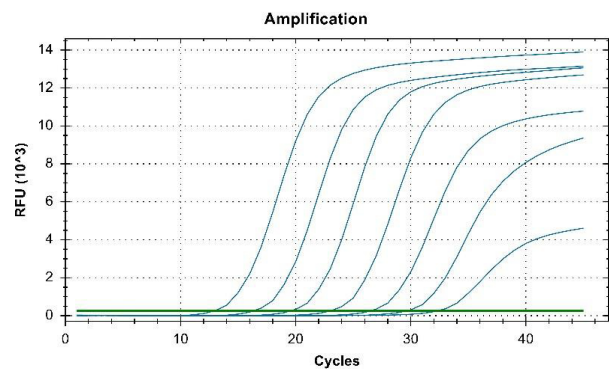
The test meets the requirements of the WHO Recommendation "Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases. Interim guidance. March 2, 2020.

- 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 ≥ 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%**

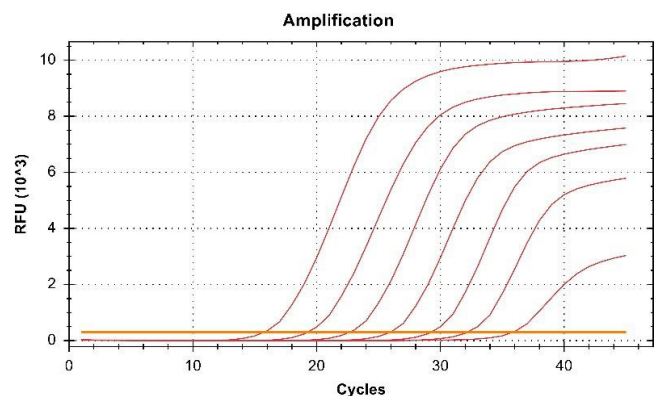
Kit components:

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

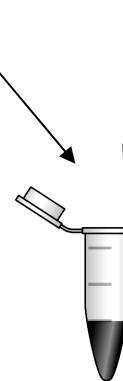
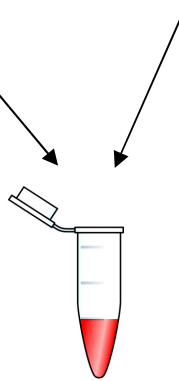
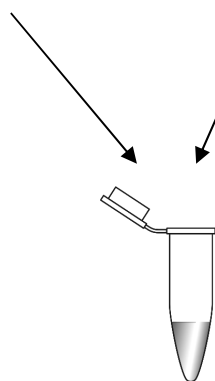
Isolation of virus genetic material

RNA SARS-CoV-2

15 μ L Rehydration Buffer
+ 5 μ L Negative control

15 μ L Rehydration Buffer
+ 5 μ L RNA SARS-CoV-2

15 μ L Rehydration Buffer
+ 5 μ L Positive control



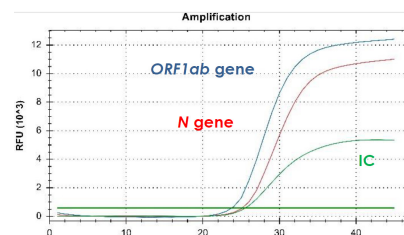
Each PCR microtube contains a lyophilized reaction mixture

Negative control

Examined sample

Positive control

Close all PCR microtubes tightly and place in thermocycler



Analysis of obtained data
Output of result