

# Detection Kit for Novel Coronavirus (2019-nCoV) RNA (Fluorescent PCR)

# Intended Use

This kit is used for the in vitro qualitative detection of novel coronavirus (2019-nCoV) ORFlab and N gene in the throat swabs, sputum specimens of suspected pneumonia patients infected by novel coronavirus, suspected clustering cases and others needing diagnosis or differential diagnosis for novel coronavirus.



# Why you choose us?

- \* Double targets labeled + endogenous internal standard control.
- \* Millions of the product have been used to detect the Novel coronavirus all around the world.
- \* Most of the CHINESE hospitals use it to detect the novel coronavirus.
- \* CE certificate got on Feb 5th, 2020.
- \* Listed on FIND.



# CE certificate and on the list of FIND



COVID-19

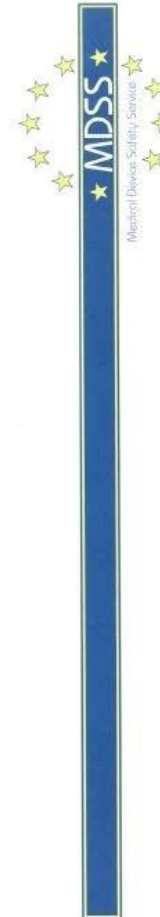
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- [DAAN Gene Co., Ltd of Sun Yat-sen University](#) Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (CE-IVD) [Contact](#)
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- [DiaSorin Molecular, LLC](#) Simplexa™ COVID-19 Direct RT-PCR Kit (CE-IVD) [Contact](#)
- [Diatheva SRL](#) COVID-19 PCR DIATHEVA Detection kit (CE-IVD) [Contact](#)
- [DNA Software, Inc.](#) Upper Respiratory Virus Panel, multiplex PCR, COVID-19, Influenza A, Influenza B, Adenovirus, Rhinovirus, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, and Human Metapneumovirus (CE-IVD) [Contact](#)
- [Dynamiker Biotechnology \(Tianjin\) Co., Ltd](#) Novel Coronavirus(2019-nCoV)RT-PCR Detection Kit (CE-IVD) [Contact](#)
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<https://www.finddx.org/covid-19/pipeline/>



## Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:



as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated Feb 05, 2020

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2020-02-05

Joy Grimm  
Senior Consultant  
MDSS GmbH

MDSS · Medical Device Safety Service · Schiffgraben 41 · 30175 Hannover, Germany



# Product in use





# International cooperation



# Test Principle

This kit is based on one-step RT-PCR technique. In practice, 2019 Novel Coronavirus (2019-nCoV) ORF1ab and N genes are selected as amplification target regions. Specific primers and fluorescent probes are designed (N gene probe is labeled with FAM and ORF1ab probe with Yellow) for the detection of 2019 Novel Coronavirus RNA in the specimens. This kit also includes an endogenous internal standard detection system (the internal standard gene probe is labeled with Cy5), which is used for monitoring over the processes of specimen collection, RNA and PCR amplification, thereby reducing false negative results

# Storage Conditions and Validity Date

The kit is stored at  $-20\pm 5^{\circ}\text{C}$ , and the validity period is 6 months.

The reagent can be stored at  $4^{\circ}\text{C}$  for 3 days; the kit can be stored at  $37^{\circ}\text{C}$  for 3 days; repeated freezing and thawing should be avoided; repeated freezing and thawing cycles should not exceed 7 times and the times of decapping the reagent should not exceed 7.

See the product label for the date of manufacture and validity of the kit.

## Applicable Instruments

ABI 7500 & LightCycler480.

**PS:More details, pls check it on the USER MANUAL**





We do business together, we fight the coronavirus together...

**EUROCAREHOLLAND B.V.**

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