

# Establishment of local cut-off

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China CDC MODPAD**



**SARS-CoV-2  
Nucleic Acid Detection  
( PCR-Fluorescence Probing)**



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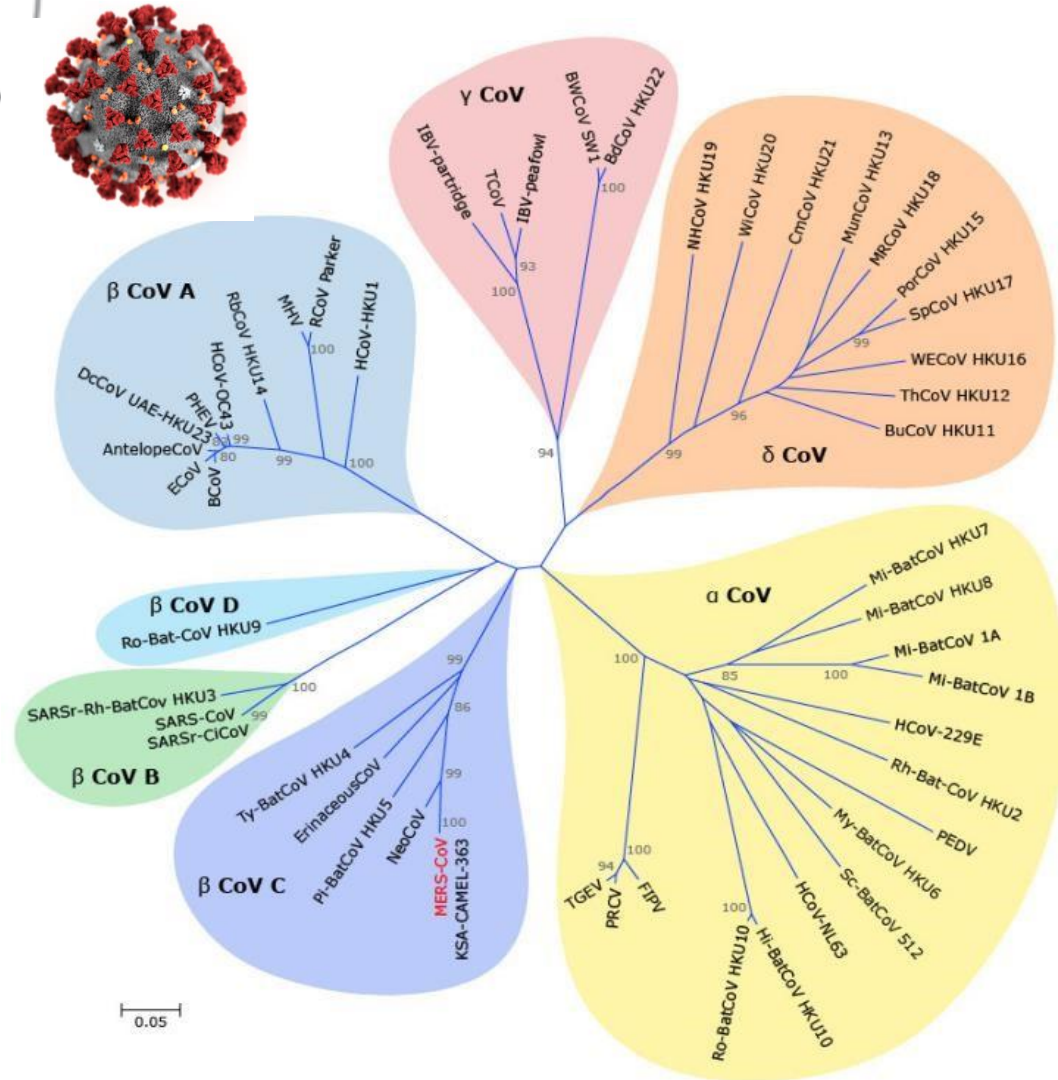
**1**  
**About the Virus**

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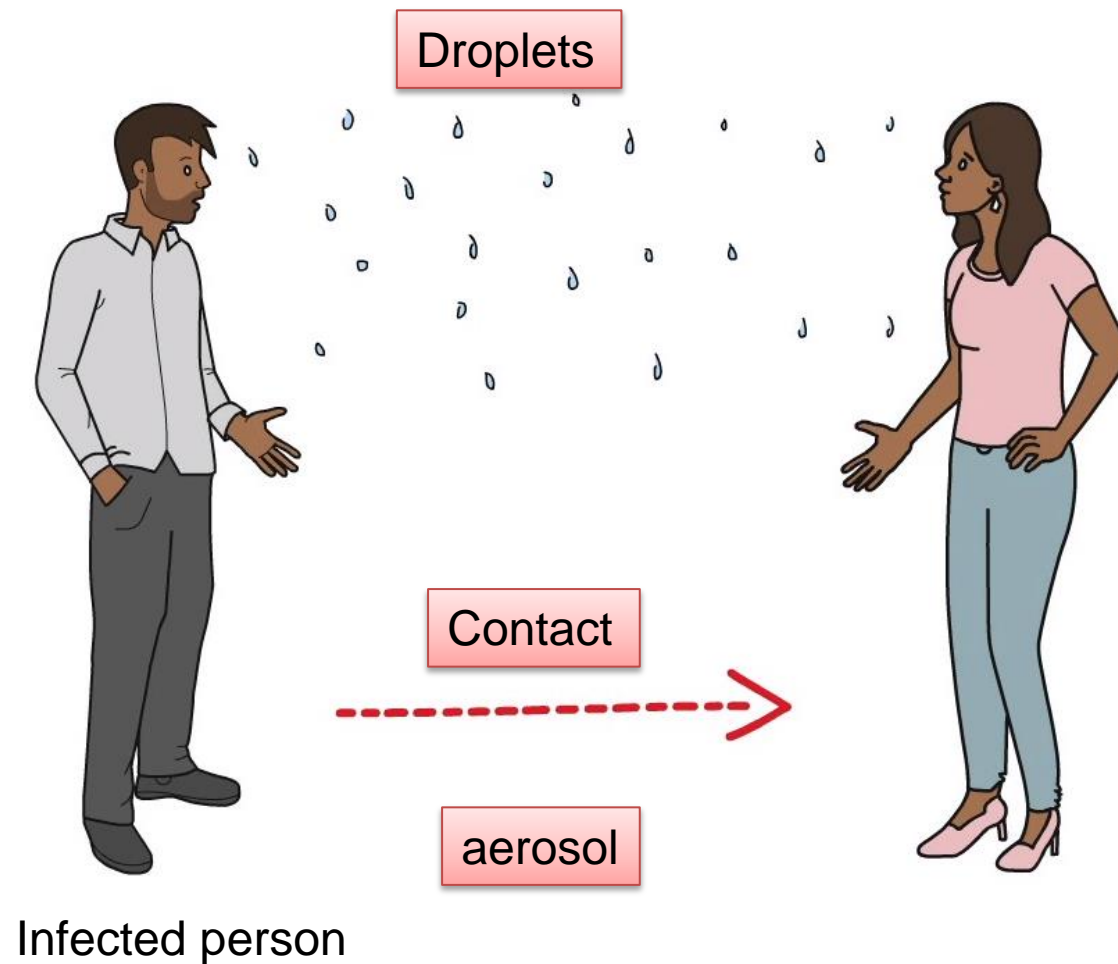
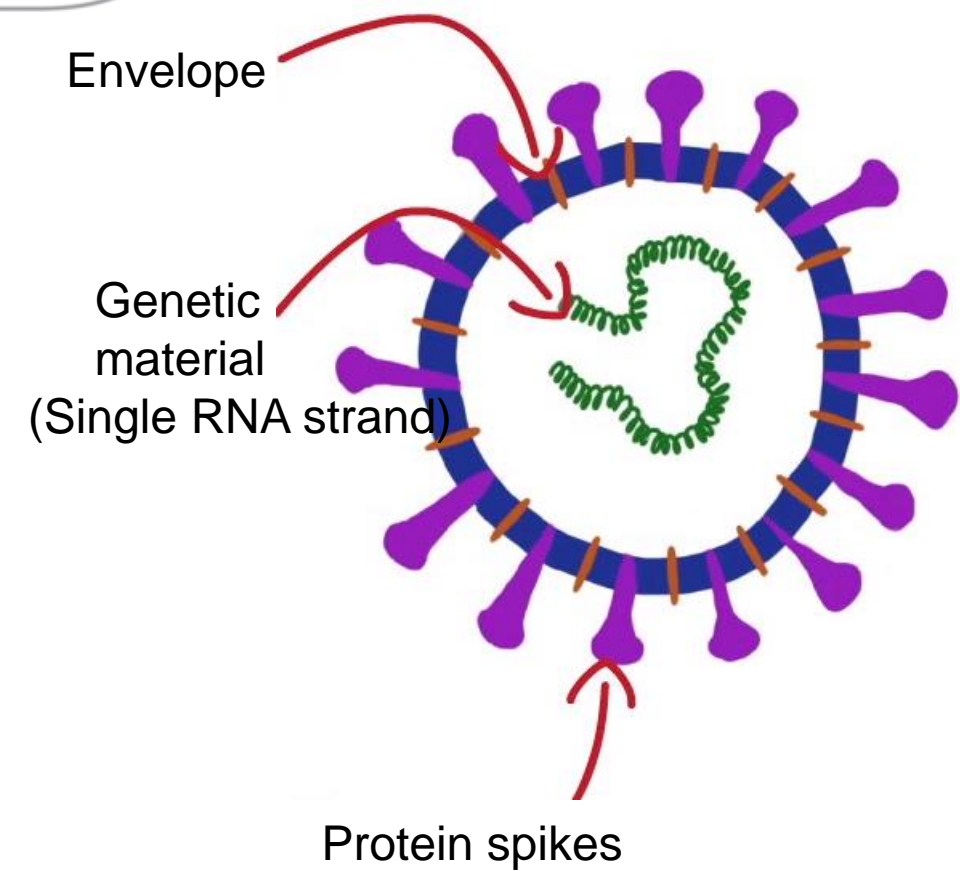
# COVID-19



COVID-19 is an infectious disease caused by SARS-CoV-2, a novel coronavirus that can cause illness in animals or humans. In humans there are several known coronaviruses that cause respiratory infections. These coronaviruses range from the common cold to more severe diseases such as SARS, MERS, and COVID-19.



# COVID-19



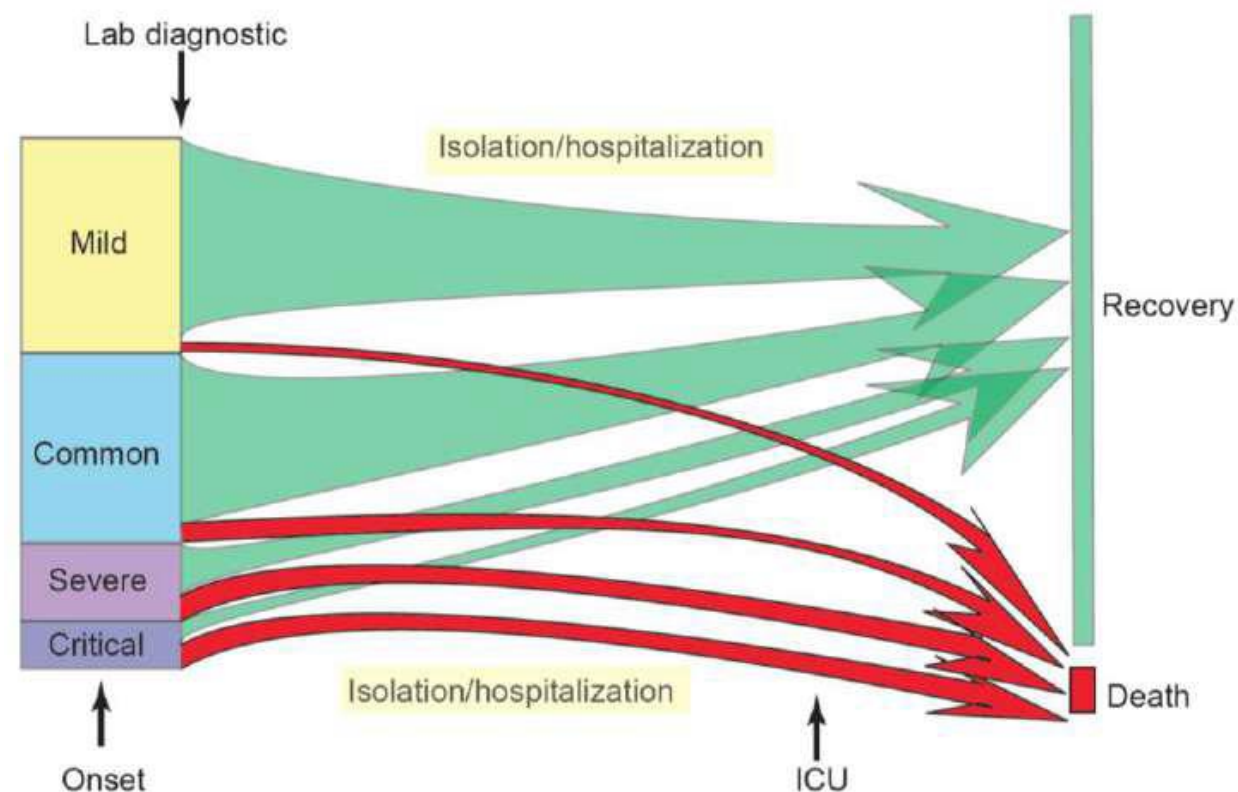
**TRANSMISSION**





## Wide range of symptoms reported:

- Fever
- Cough
- Shortness of breath or difficulty breathing
- Headache
- Nasal congestion
- Muscle pain
- Sore throat
- Loss of smell or taste
- Diarrhea (may be present in some patients)





## TREATMENT

**I. Currently, care for patients is primarily supportive:**

Relieve symptoms

Manage respiratory, and other organ, failure

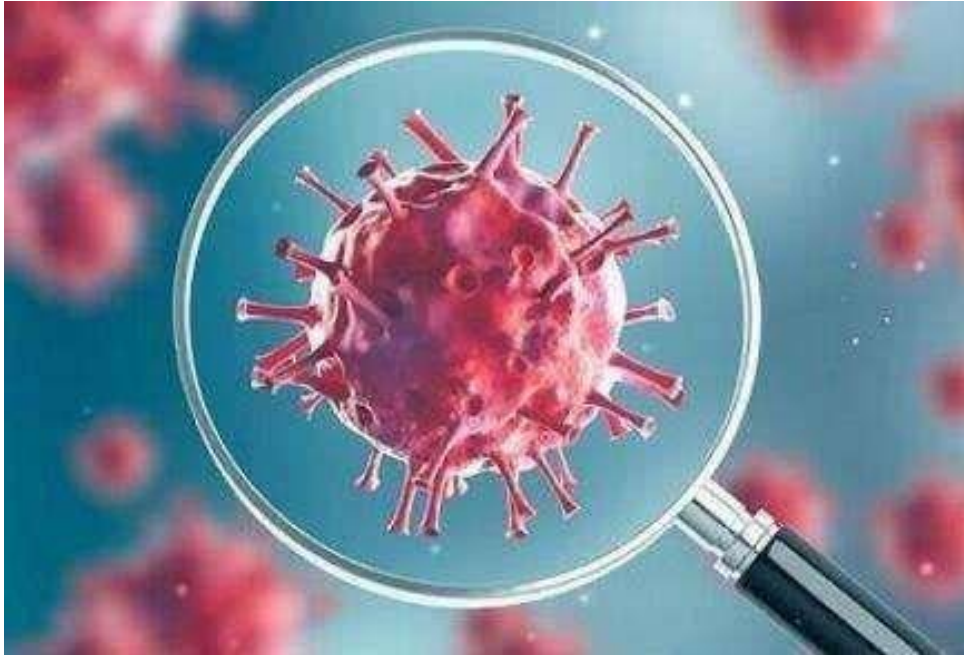
**II. There are no specific antiviral treatments currently licensed for COVID-19**

**III. No vaccine is currently available**





## HOW TO TEST SARS-CoV-2



- I. Real-time RT-PCR testing
- II. Antibody detection
- III. Antigen detection
- IV. Blood Test
- V. CT

# China: nucleic acid positive is the gold standard of laboratory diagnosis

## 新型冠状病毒肺炎诊疗方案 (试行第八版)

新型冠状病毒肺炎（新冠肺炎，COVID-19）为新发急性呼吸道传染病，目前已成为全球性重大的公共卫生事件。通过积

### (二) 确诊病例。

疑似病例同时具备以下病原学或血清学证据之一者：

1. 实时荧光 RT-PCR 检测新型冠状病毒核酸阳性；
2. 病毒基因测序，与已知的新型冠状病毒高度同源；
3. 新型冠状病毒特异性 IgM 抗体和 IgG 抗体阳性；
4. 新型冠状病毒特异性 IgG 抗体由阴性转为阳性或恢复期

IgG 抗体滴度较急性期呈 4 倍及以上升高。

From the first edition to the eighth edition,

**COVID-19 diagnosis and treatment protocol always proposed that fluorescence real-time RT PCR detection is the gold standard of diagnosis .**

confirmed cases should be tested positive by fluorescent rRT-PCR for nucleic acid of SARS-CoV-2.



# China: nucleic acid testing is the standard of exclusion, discharge and isolation

## Case Management

- Suspected case exclusion:
- The SARS-CoV-2 **nucleic acid test was negative** for two consecutive samples (the sampling interval was at least 24h apart)
- SARS-CoV-2 specific IgM and IgG antibodies remained negative 7 days after onset

## Post-discharge management

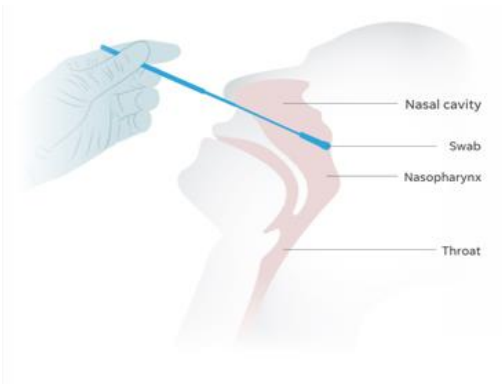
- Discharge standards:
  - The **nucleic acid test** results of two consecutive sputum and nasopharyngeal swabs and other respiratory tract specimens were **negative** (sampling interval was at least 24h)
  - Follow-up and examination of respiratory specimens were strengthened after discharge

## Asymptomatic infection management

- quarantine for 14 days
- In principle, a person can be released from quarantine after 14 days if nucleic acid tests of SARS-CoV-2 are negative



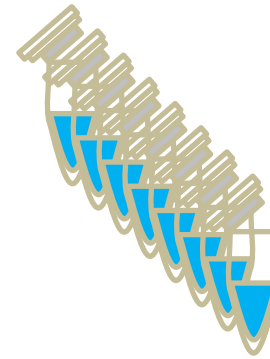
# REAL-TIME PCR TESTING



Step 1.  
Collect sample



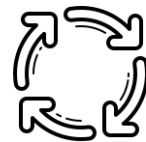
Step 2.  
Nucleic acid extraction



Step 3.  
Prepare master mix



Step 4.  
Run the program



*The whole process took around 90 minutes*



## REAL-TIME PCR TESTING

### Notice:

1. The technicians engaged in SARS-CoV-2 specimen collection should have biosafety training and relevant experimental skills. The quality of specimen is important in Real-Time PCR test.
2. The virus detection rate in sputum samples is high. But the sputum samples are usually very thick. So here are some good practice:
  - 1) 1g/L Phosphate Buffer for Protease K
  - 2) Phosphate Buffer with 0.1g Dithiothreitol (DTT) and 0.78g Sodium Chloride (table 1)

Table 1 Sputum digestive fluid storage fluid formula

Component	Mass/Volume
Dithiothreitol	0.1g
NaCl	0.78g
PCl <sub>3</sub>	0.02g
Na <sub>2</sub> HPO <sub>4</sub>	0.112g
KH <sub>2</sub> PO <sub>4</sub>	0.02g
H <sub>2</sub> O	7.5ml
PH: 7.4±0.2 (25 °C)	



## REAL-TIME PCR TESTING

Notice:

3. Stool specimen: 1ml specimen processing solution was taken, and a stool specimen about the size of soybean was added to the tube. Vortex 5 mins and centrifuged at 8000 rpm for 5 minutes, and the supernatant was kept for detection. (table 2)
4. Sample preservation: Specimens used for virus isolation and nucleic acid testing should be tested as soon as possible, and those that can be tested within 24 hours can be stored at 4° C; Specimens that cannot be detected within 24 hours should be stored at or below -70° C (or temporarily stored at -20° C if no -70° C is available). Serum specimens can be stored at 4° C for 3 days and below -20° C for a longer time.

Table 2 Stool specimen processing solution formula

Component	Mass/Volume
Tris	1.211g
Sodium Chloride	8.5g
Anhydrous Calcium Chloride	1.1g
H <sub>2</sub> O	800ml
PH: 7.5 (25 °C)	

**\*Adjust pH to 7.5 with concentrated hydrochloric acid and replenish to 1000 mL with deionized water**



## REAL-TIME PCR TESTING

Notice:

5. Reporting result: For SARS-CoV-2 targets : Ct value  $\leq 38$  is considered positive(+) ; Ct value  $> 40$  is considered negative(-) ;  $38 < \text{Ct} \leq 40$  is considered diagnostic gray zone. For RNase P: Ct value  $\leq 38$  is considered positive (+); Ct value  $> 38$  is considered negative (-)
6. Reporting positive
  - (1) ORF1ab and N gene both positive.
  - (2) One of two target genes is positive. resampling and retesting, if positive again, then positive
7. Trouble shooting in Reporting
  - (1) One target gene is in the diagnostic gray zone and the other target gene is negative. (2) Both of two target genes is in the gray zone. Under these circumstances, repeating nucleic acid extraction is suggested and then amplifies simultaneously with previous template. If both results show positive then report positive, otherwise report suspicious. When suspicious is reported, consider the following actions: (1) change other manufacturer's kit or different method with superior sensitivity such as digital PCR to further confirm. (2) Repeat sampling or collect specimen from different parts of the patient and repeat the test.
8. Reporting negative

Report “negative” when none of both target genes shows result. It is possible due to low viral load and should be analyzed by combining clinical sign. Repeat sampling or collect specimen from different parts of the patient and repeat the test when clinical sign and other examinations are high suspected.





## WHERE TO DO THE TEST



### I. PCR Laboratory

- CDC Center



- Public & Private Labs

# COVID-19 CORONAVIRUS REAL TIME PCR KIT

Approved by CE, NMPA, FDA-EUA, WHO-EUL



COVID-19 Coronavirus Real Time PCR Kit

Catalog

JC10223-1NW

Package

50 Tests/Kit

## Features:

- **Multiplex** real-time PCR technology
- **ORF1ab and N-genes** target region
- Genes of RnaseP Internal Control (IC)
- **72 minutes** Assay runtime
- Clinical Sensitivity: **94.9%**
- Clinical Specificity: **98.7%**
- Limit Of Detection: **350 copies/mL**
- Sample Input Volume: **5  $\mu$ L**
- Storage Temperature: **-20 $\pm$ 5 $^{\circ}$ C**
- Transportation Temperature: **-25~8 $^{\circ}$ C**
- Shelf Time : 6 months

## Sample Type:

- Nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs.
- Nasal aspirates, nasal washes, bronchoalveolar lavage (BAL) fluid and sputum specimens.

# COVID-19 CORONAVIRUS REAL TIME PCR KIT

## Main advantage

- Shorter time, more efficient: The runtime within **72 minutes** which normally 90-150 minutes
- Large size sample validation: more than **9000000 samples**
- Better performance parameter:  
Clinical Sensitivity: **94.9%**  
Clinical Specificity: **98.7%**
- Lower detection limit: The LOD is **350 copies/mL**, which make less chance to miss any low concentration of the samples



COVID-19 Coronavirus Real Time PCR Kit

# CERTIFICATES AND EVALUATION

## RESULTATS D'EVALUATION DE LA PERFORMANCE POUR LA DETECTION DU SARS-CoV-2 PAR COMPARAISON AVEC LA TECHNIQUE DE REFERENCE DU CNR



Nom du Kit : COVID-19 Coronavirus Real Time PCR Kit

Fournisseur : bioPerfectus technologies

Détection : 2 cibles + 1 contrôle endogène

### Laboratoire Investigateur

Pr Sylvie van der Werf ([sylvie.van-der-werf@pasteur.fr](mailto:sylvie.van-der-werf@pasteur.fr))

Dr Sylvie Behillil ([sylvie.behillil@pasteur.fr](mailto:sylvie.behillil@pasteur.fr))

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### CONCLUSIONS

Le Centre National de Référence des Virus des Infections Respiratoires (dont la grippe) considère que le kit COVID-19 Coronavirus Real Time PCR possède une sensibilité de détection du SARS-CoV-2 acceptable.

La spécificité du kit n'a pas été évaluée.

Paris, le 18/06/2020

Pr. Sylvie van der Werf



FDA U.S. FOOD & DRUG  
ADMINISTRATION

June 18, 2020

Xu Jiafa  
Jiangsu Biopertectus Technologies Co., Ltd.  
Taizhou National Medical, Hi-tech Development Zone  
Taizhou, Jiangsu, CHN 225300

Device: COVID-19 Coronavirus Real Time PCR  
Company: Jiangsu Biopertectus Technologies Co., Ltd.  
Indication: Qualitative detection of SARS-CoV-2  
nasopharyngeal swabs, oropharyngeal  
nasal swabs, mid-turbinate nasal swab  
washes, bronchoalveolar lavage (BAL)  
individuals who are suspected of COVID-19  
provider. Emergency use of this test in  
laboratories.

Authorized Laboratories: Laboratories certified under the Clinical  
Amendments of 1988 (CLIA), 42 U.S.C.  
requirements to perform high complexity testing.



World Health  
Organization

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In reply please  
refer to: DH/vl

Your reference: P17-370-9

Jiangsu Biopertectus Technologies Co., Ltd  
Attention: Dr Jin Wei  
R&D Director  
3F, Bldg G19, N0.1 Medical City Avenue  
Taizhou City  
Jiangsu Province  
China (Republique populaire de)

9 July 2020

Dear Dr Wei,

Subject: WHO Emergency Use Listing (EUL) - Product eligible for listing

Product name: COVID-19 Coronavirus Real Time PCR Kit  
Application number: EUL 0515-202-00  
Product codes: JC10223-1NW-50T  
Regulatory version: CE marked version

We are pleased to inform you that the above-referenced product was listed as eligible for WHO procurement on 9 July 2020. The EUL listing can be leveraged by other international, regional and national procurement agencies. The product will be eligible for procurement for 1 year, unless circumstances dictate otherwise.

For further information kindly check:

<https://www.medrxiv.org/content/10.1101/2020.02.12.20022327v2>

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>



## Evaluation in Russia

## Certification in Australia

## Certification in Thailand





China's first mobile nucleic acid testing laboratory

Help Xinjiang fight COVID-19



Support Chinese Medical Team to help Guyana

Donation by WHO

# BIOGERM

- Approved by National Institutes for Food and Drug Control (national reference product)
- Approved by Quality SuBeijing Center for Medical Device pervision and Testing of State Food and Drug Administration
- BioGerm's 2019-nCoV Nucleic Acid Detection Kit has already tested more than **3 million** specimens in China at 600 units
- **Now, the national and provincial CDC, Beijing and Shanghai customs all use BioGerm's PCR testing products for detection of entry personnel for the 2019-nCoV**



**>280**  
hospitals



**>300**  
CDC



**>50**  
customs and  
ports



**>12**  
meidical laboratories  
all over China

**Thank you !**