

2020 | Marketing Dept.

# **Novel Coronavirus 2019-nCoV (ORF1ab/E/N gene) Nucleic Acid Detection Kit (Fluorescence PCR) Product Introduction**

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01

**2019-nCoV**

**About The Program**

# 2019-nCoV About The Program

Since mid-December 2019, cases of unexplained pneumonia with fever, fatigue, cough, and dyspnea as the main symptoms have occurred in Wuhan, China for a short period of time. Governments at all levels and administrative departments of health care attach great importance to quickly organizing Medical units and research institutes carry out investigations, treatments and collaborative research. Quickly determined the pathogen of these cases as **new coronaviruses**.

# 2019-nCoV About The Program

The World Health Organization (WHO) has confirmed and named it as 2019-nCoV, and the pneumonia caused by the pathogen infection is called Novel Coronavirus Pneumonia.

# Clinical manifestations of 2019-nCoV patients after infection

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## **General symptoms:**

Fever, fatigue, dry cough, dyspnea gradually appear, and some patients have mild onset symptoms without fever.

## **Severe symptoms:**

Acute respiratory distress syndrome, septic shock, difficult-to-correct metabolic acidosis, coagulopathy.

*Remarks: Most patients are mild to moderate with good prognosis, and a few patients are critically ill and even die.*

# Laboratory-confirmed Methods for 2019-nCoV Infected Patients

In the **early stages** of the disease, the total **number of white blood cells** in the peripheral blood was **normal or decreased**, the **lymphocyte count decreased**, and some patients had **increased liver enzymes, muscle enzymes, and myoglobin**.

# Laboratory-confirmed Methods for 2019-nCoV Infected Patients

Most patients have elevated **C-reactive protein (CRP)**, erythrocyte sedimentation rate and normal **procalcitonin**. In severe cases, **D-dimer increases** and **peripheral blood lymphocytes progressively decrease**.

New coronavirus nucleic acids can be detected in throat swabs, sputum, lower respiratory tract secretions, and blood.

# Maccura Products for laboratory Inspections



Item	Platform	Product ( Maccura )
Blood Cell Analysis	Hematology	F 560/F 580、 F 800 Series ( End of March )
Liver Enzyme : ALT、 AST、 LDH、 ALP、 GGT、 CHE	Clinical Chemistry	Biochemical Reagents and Supporting Instruments
Muscle Enzyme : CK、 CK-MB		
Renal Function : Urea、 Crea、 UA		
C-reactive protein	Clinical Chemistry / Immunoassay	Biochemical Reagents / R-01
Myoglobin	Immunoassay	i 3000
Procalcitonin		i 3000 / IS 1200 / R-01
D-dimer	Clinical Chemistry / Coagulation	Biochemical Reagents and Supporting Instruments / H 2600
Nucleic Acid Detection	Molecular Diagnosis	Molecular reagents and related instruments
Urine routine, ESR, Blood Gas		



02

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2019-nCoV ( ORF1ab/E/N gene

Product Introduction

# Maccura 2019-nCoV Product Introduction

( Extraction + Amplification )

Two steps of detection:

**1st step is to extract virus RNA from the sample.**

**2nd step is to perform RNA amplification.**

*A total of two reagent products are needed, both of which are produced by Maccura.*

Note : Features of emergency approval products :

- 1、 The product validity period on the registration certificate is described as "tentatively valid for 6 months" ;
- 2、 Registration certificate is valid for "1 year"

# Maccura 2019-nCoV Product Introduction

( Extraction + Amplification )

Process	Type	Product	Specification	Validity	Sample Type
1 <sup>st</sup> step: Extraction	Analyzer Mating Reagent for Auto Extraction	Nucleic acid (RNA) extraction kit (magnetic bead method)	32 Tests/ Kit	12 months	Respiratory secretions (throat swabs, nasal swabs, nasopharyngeal extracts, deep cough sputum, respiratory extracts, bronchial lavage fluid).
	Reagent for Manual Extraction	Nucleic acid (RNA) extraction kit (magnetic bead method)	48 Tests/ Kit	12 months	
2 <sup>nd</sup> step: Amplification	Analyzer Mating Reagent for Auto Amplification	New Coronavirus 2019-nCoV (ORF1ab / E / N Gene) Nucleic Acid Detection Kit	32 Tests/ Kit	6 months ( note 1 )	

*Note 1 : Features of emergency approval products :*

- 1, The product validity period on the registration certificate is described as "tentatively valid for 6 months" ;*
- 2, Registration certificate is valid for "12 months"*

# Maccura 2019-nCoV Flexible Solutions

( Extraction + Amplification )



Process	Existing Instrument Solution	Kit Solution	NOTE
<b>1<sup>st</sup> step: Extraction</b>	<b>Option 1:</b> With Allsheng Auto-Pure 32A	Maccura Analyzer Mating Reagent for Auto Extraction	
	<b>Option 2:</b> With automatic nucleic acid extraction instrument of other brands but not Allsheng	Other Brand' s Reagent for Auto Extraction	
	<b>Option 3:</b> No nucleic acid extraction instrument	Maccura Reagent for Manual Extraction	Manual extraction process is complicated, and application training is required.
<b>2<sup>nd</sup> step: Amplification</b>	Amplifier ( <u>4-test channels and above are satisfied</u> ): Such as ABI 7500、ABI Q5、Roche Lightcycler 480II、HONGSHI SLAN-96P	Amplification (Required)	

03

# Maccura 2019-nCoV Product Advantages

# Maccura 2019-nCoV Product Advantages

- **Triple detection to prevent missed detection :**

Simultaneous detection of the **three genes** of **ORF1ab / E / N** in 2019-nCoV, meeting the requirements of relevant documents of the World Health Organization (WHO)

- **Add internal standard and monitor the whole process :**

For each test, an internal standard is added to the test reagent to prevent false negative test results.

- **Simulate viruses to ensure quality :**

The positive control and internal standard of the kit are **simulated RNA virus particles**, which are closer to the detection of the virus structure, contain protein envelopes, and participate in the extraction with the sample at the same time, better monitor the entire experimental process and ensure the reliability of the test results

- **Optimized processes, efficient and safe :**

Reagent and instrument matching verification to optimize the testing process. It takes only **two hours** from safe sample processing to stable testing data output, which improves the testing speed and protects the safety of front-line workers.

04

Q&A



Question: What are the prerequisites for users to carry out 2019-nCoV testing?

Answer:

1. The user needs a **special molecular laboratory**.
2. A PCR amplification instrument **with four channels or more** is required.
3. An automatic nucleic acid extraction instrument is required.

*(If there is no full-automatic instrument, manual extraction is also possible, but the manual extraction process is more complicated, requiring technical staff to train customers, and manual extraction needs to provide auxiliary equipment such as a magnetic stand. Manual extraction is not recommended in the early stage, and the company waits for notification afterwards.)*

# Q&A

Question: What types of PCR amplification equipment can match our reagents?

Answer:

1. Theoretically, the instrument has four or more fluorescence detection channels. At present, it is clear: **ABI 7500, ABI Q5, Roche Lightcycler 480II, Hongshi SLAN-96P, SLAN-96S**
2. If the user does not have the above-mentioned instrument, the user's existing instrument model + picture can be fed back to the marketing department, and the marketing department will assist to determine whether the instrument can be used. Theoretically, Bio-rad, Hangzhou Bioer, and Xi'an Tianlong all have amplifiers with four channels or more.

# Q&A

Question: What are the end users of 2019-nCoV?

Answer:

The main end users are the inspection department and the centers for Disease Control.

# Q&A

Question:

What is the number of samples per hour for Maccura 2019-nCoV detection solution?

Answer:

Extraction (Maccura Auto Extraction) + Amplification: **96 samples in 2 hours**

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**THANKS**

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