

## Anti-COVID-19(2019-nCoV) IgM/IgG Diagnostic Kit (Colloidal Gold)

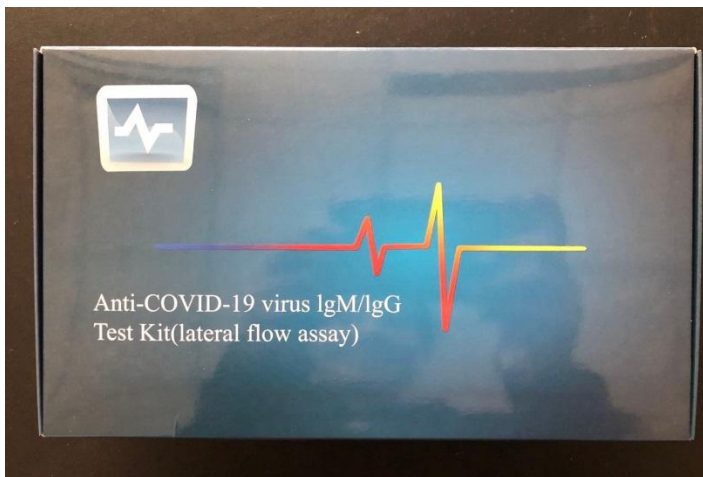
### Introduction:

The detection kit is used for detecting whether anti-COVID-19(2019-nCoV) IgM/IgG exist in human whole blood/serum/plasma. Assist clinicians to identify patients with recent COVID-19(2019-nCoV) infection.



### Product advantages:

- Easy to use
- Fast reaction
- High accuracy



### Product Specifications:

No.	Name	Format	Componet
1.	Anti-COVID-19IgM/IgG Test Card	20 stirps	mouse anti-human IgG mAb, mouse anti-human IgM mAb, Goat anti-mouse IgG pAb, colloidal gold labeled recombinant antigen protein of COVID-19, nitrocellulose membrane, glass fiber pad, absorbent paper pad, PVC backing, plastic enclosure, desiccant bag, aluminum foil bag
2	IgM/IgG sample dilution buffer	20 tubes	0.01M pH7.4 Phosphate Buffered Saline
3	Micro-quantitative sampling pipette(10ul)	20 pcs	Polyethylene (PE), Soda-lime glass
4	Double Capsule Pipette	20 pcs	Polyethylene (PE)
5	Lancet	20 pcs	Stainless steel, Polyethylene (PE)
6	Manual	1	

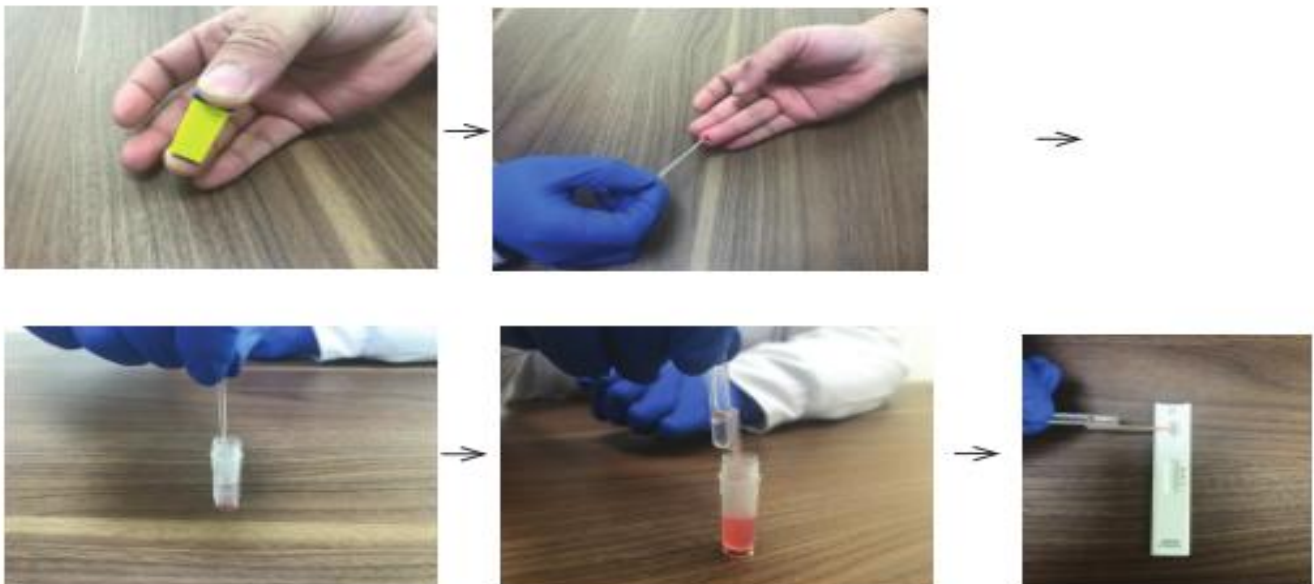


**Package:**

Inner packaging: 20 pcs / box, box size: 150\*122\*69 mm

**Storage:**

1. The test kit has to be stored at a temperature between +4°C to +30°C. Do not freeze. Unopened, all test kit components are stable for 12 months.
2. If the aluminum foil bag was opened, the strip should be used in 30 minutes.





## EC Declaration of Conformity

*Manufacturer:*

H&Z Life Science co. LTD

Address: Room 247, building E, building 3, international student entrepreneurship park, No.32 Zhujiang road, Yantai development zone, Shandong province, China.

*whose single Authorized Representative:*

Name: Luxus Lebenswelt GmbH  
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DIMDI Code: DE/0000047791  
Tax Number: DE305829099  
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We, the manufacturer, herewith declare that the products

Anti-COVID-19(2019-nCoV) IgM/IgG Diagnostic Kit (Colloidal Gold)

Model: HZ-jtj-01

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to In Vitro Diagnostic Medical Devices Directive 98/79/EC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to In Vitro Diagnostic Medical Devices Directive 98/79/EC.

following the procedure relating to the EC Declaration of Conformity set out in Annex III of Directive 98/79/EC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

H&Z Life Science co. LTD

Room 247, building E, building 3, international student entrepreneurship park, No.32 Zhujiang road, Yantai development zone, Shandong province, China.

Yantai Mar.10<sup>th</sup>, 2020  
Place, date

EC Declaration of Conformity  
VM/CE-02 (Revision A/0)