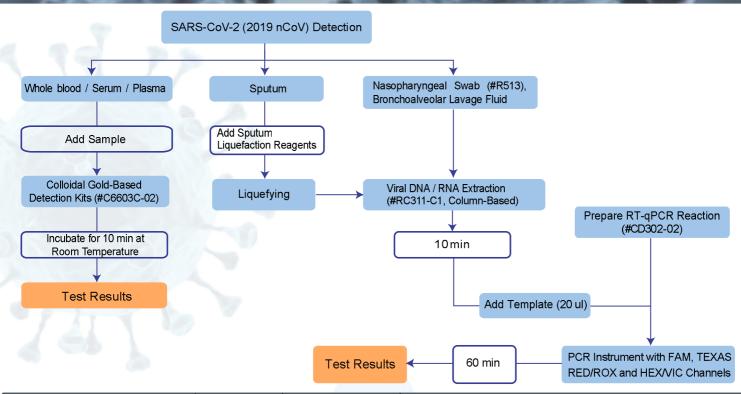


# Vazyme Solutions for SARS-CoV-2 (2019-nCoV) Detection



Product	Cat.#	Size	Introduction
Virus Sample Stabilizer	R513-01	50 tubes, 1.5 ml / tube	Applicable to specimen collection from human nasopharyngeal swab
(with Nasopharyngeal Swab)	R513-02	50 tubes, 3 ml / tube	specimen and nucleic acid preservation.
Product	Cat.#	Size	Introduction
FastPure Viral DNA/RNA Mini Kit	RC311-C1	100 tests / kit	Applicable to specimen collection from plasma, serum, nasopharyngeal swabs, sputum, bronchoalveolar lavage fluid, ascites, supernatant of cultured cell and urine.
Product	Cat.#	Size	Introduction
2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	CD302-02	100 tests / kit	1) Adding 20 ul of extracted RNA to increase detection sensitivity and reduce false negatives; 2) Positive control (2019-nCoV-pseudoviruse) provides a nucleic acid extraction and a reverse transcription control to validate the entire procedure and reagent integrity. 3) Internal control (RNAse P gene) provides a nucleic acid extraction procedural control and a secondary negative control.
Product	Cat.#	Size	Introduction
2019-Novel Coronavirus (2019-nCoV)	000000 00	50 to sta 11:11	Applicable to detection of 2019-nCoV lgG / lgM antibodies from human



IgG / IgM Detection Kit (Colloidal Gold-

Based)



50 tests / kit

C6603C-02





Applicable to detection of 2019-nCoV IgG / IgM antibodies from human

whole blood, serum or plasma within 10 min. No instruments needed.



# 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)

### 1. Product Information

Product Name: 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)

Cat.#: C6603C-02 Size: 50 tests / kit

Certificate: FDA (Submission#: PEUA200226), CE - IVD, CFDA, ISO 13485, Singapore HSA,

Philippines FDA

### 2. Features

Rapid Test within 10 min. No additional instruments needed.

- Certificated by CFDA, CE, HSA, and FDA (Submitted)
- Clinical test for 2000+ samples.
- Wildly used in multiple hospitals and CDCs in Hubei (including Wuhan), Hunan, Jiangsu, Guangdong, Henan, Hebei, etc.
- Exported to Germany, Poland, Japan, Singapore, Indonesia, etc.

# 3. Pictures





## 4. Package

Per Kit (50 tests / kit): 270 \* 132 \* 110 mm, NW 0.56 kg, GW 0.6 kg

Per Shipping Box (12 kits / box): 560 \* 280 \* 370 mm, NW 7.2 kg, GW 8.0 kg

Number of tests per shipping boxes: 12 Kits / 600 Tests;



# 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)

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3822009000



# 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)

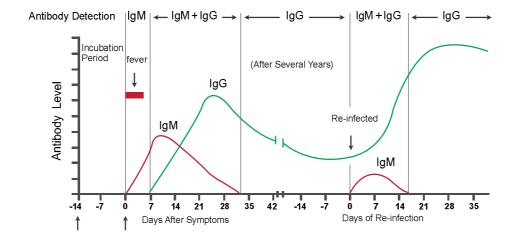
Rapid detection within 10 min. No equipments required.



# IgM and IgG Antibodies

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019-nCoV. Some patients with negative results in nucleic acid test show positive in IgM test, indicating that the IgG / IgM detection is one of the effective methods for the diagnosis of 2019-nCoV.

The level of IgM antibody begins to rise after 1 week after the initial infection, while the IgG appears later than IgM (usually in 14 days after infection) and can last for 6 months or even several years, which means that the IgG serves as an indicator of previous infection. Suspected patients that are infected by 2019-nCoV can be rapidly identified by simultaneous monitoring of IgM and IgG. During the outbreak period of 2003-SARS and the 2016-Zika, IgM / IgG antibody detection was used as one of the recommended diagnostic methods.



# Advantages of IgG / IgM Detection

Indicating both recent infections and previous infections, reducing missed detection rates.

Low requirements of instruments; suitable for primary hospitals and conventional outpatient clinics.

Blood testing; low requirements for sampling; no special virus collection tube required.

Suitable for combined detection with nucleic-acid testing kit to improve the diagnosis rate of suspected patients.

02

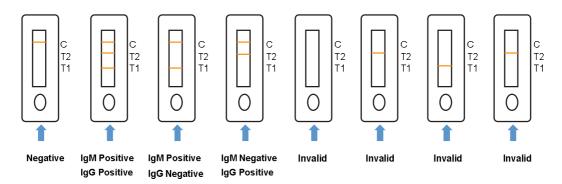
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# 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)

# **Product Advantages**

- 01 Rapid-screening within 10 minutes.
- 02 High detection efficiency: simultaneous monitoring of IgM and IgG.
- Detection without any equipments.
- Easy to operate, and is compatible with serum/ whole blood/ plasma.
- 05 Room-temperature storage.

# Interpreting Test Results

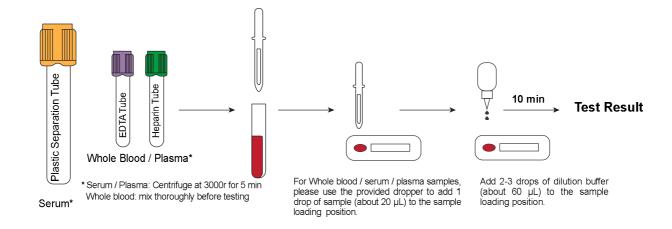


Results	Interpreting
IgM positive, IgG positive	Indicates that it may be a recent infection with 2019-nCoV.
IgM positive, IgG negative	Indicates that it may be a recent infection with 2019-nCoV.
IgM negative, IgG positive	Indicates that it may be a previous infection with 2019-nCoV.
IgM negative, IgG negative	Indicates that it may be no infection with 2019-nCoV, or there is not enough detectable antibodies in the early infection.

# **Product Information**

Product Name	2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)	
Size	50 Tests / Kit	
Specimen	Serum / Plasma / Whole Blood	
Required Volume of Specimen	20 ul	
Storage	4℃ - 30℃. Sealed.	

# Workflow







# 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based) Instruction for Use

### Intended Use

This product is intended to detect the IgG / IgM of 2019-Novel Coronavirus (2019-nCoV) from human serum, plasma and whole blood.

# IgM / IgG Antibody

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019nCoV. Normally, the level of IgM begins to rise after 1 week after the initial infection, while the IgG appears later than IgM (usually about 14 days after infection). Suspected patients that are infected by 2019-nCoV can be rapidly identified by simultaneous monitoring of IgM and IgG.

# Workflow 10 min Separation Test Result Heparin Plastic Whole Blood / Plasma For Whole blood / serum / plasma samples, please use the provided dropper to add 1 Add 2-3 drops of dilution buffer (about 60 $\mu$ L) to the sample \* Serum / Plasma: Centrifuge at 3000r for 5 min Whole blood: mix thoroughly before testing drop of sample (about 20 µL) to the sample loading position T2 T2 Т2 T2 Т2 Т2 Positive: At least one red test line (T1, T2 line) Negative: Only one red quality control line Invalid: No red quality control line (C line) appears in the and one red quality control line (C line) appear in (C line) appears in the detection area. detection area (e.g. without any red lines or only test lines (T1, T2 line). the detection area

### Interpreting Test Results

Positive: (1) If asymptomatic, it is recommended to use the nucleic acid detection kit to test again immediately;

(2) If symptomatic, it is recommended to go to the hospital immediately.

Negative: (1) If asymptomatic, indicates that there is no novel coronavirus infection; (2) If symptomatic, it is recommended to use the nucleic acid detection kit to test again immediately.

Invalid: It is recommended to test again in strict accordance with the operating instructions.

After the detection, all the test strips should be treated as medical wastes.