



COVID-19 IgM/IgG Rapid Kit

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TECHNICAL SPECIFICATIONS

NAME

COVID-19 IgM/IgG Rapid Kit

TYPE OF TEST

SEROLOGICAL RAPID BLOOD TEST

CERTIFICATION

CE, GMP, ISO, (FDA emergency approval application)

SUMMARY

COVID-19 IgM/IgG Rapid Kit is a supplementary detection indicator for suspected cases with negative nucleic acid Detection, or in conjunction with PCR in diagnosis of suspected cases

SPECIFICATION

Item	Specification
Detection Target	SARS-CoV-2
Detection Technology	Serological Rapid Blood Test
Specimen Type	10 µL of whole blood, serum or plasma
Test Results	10-15 minutes
Accuracy	97% sensitivity and specificity

FEATURES

- Fast and easy to use in emergency.
- Detect and differentiate IgM/IgG antibody specific to SARS-CoV-2.
- Require small sample volume (10 µL of whole blood, serum or plasma).
- No special equipment or training needed.

LOGISTICS INFORMATION

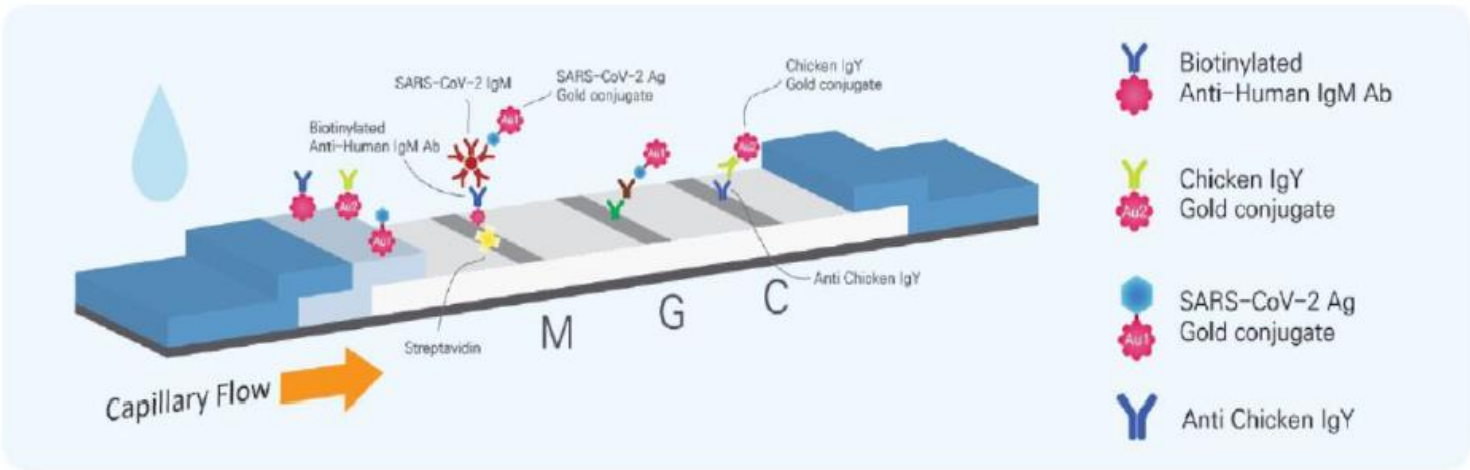
- Packing condition:
 - One small box = One kit = 25 tests
 - One Carton = 32 kits = 55x41x41 cm
 - Total weight per carton 17.50 Kg.
- Packing Box:
 - One pallet size 110x110x12 cm
 - One pallet = 12 Cartons.
- Temperature of Storage: 1-40 °C (34-104°F)
- Shelf life: 12 months
- Kit Component:
 - Test Cassette
 - Disposable capillary piette
 - Assay buffer vial
 - Instructions for use



COVID-19 IgM/IgG Rapid Kit



Test Method



* Immune chromatography using colloidal gold

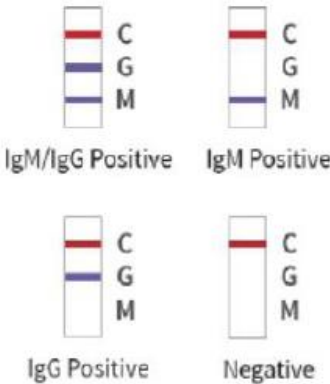
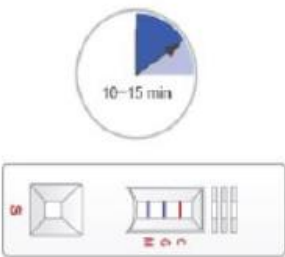
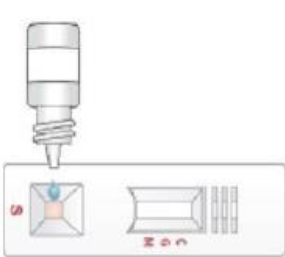
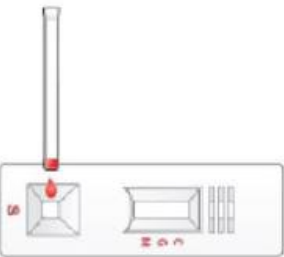
Clinical Performance

SARS-CoV-2	careUS™ COVID-19 IgM/IgG
Clinical sensitivity (IgM and/or IgG)	93.6% (95% CI: 82.8% ~ 97.8%)
Clinical specificity	98.0% (95% CI: 89.5 ~ 99.6%)

- Out of 47 SARS-CoV-2 positive samples confirm by the RT-PCR, the COVID-19 IgM/IgG Rapid Kit detected 44 positive samples (93.6%).
- Out of 50 SARS-CoV-2 negative samples confirm by the RT-PCR, the COVID-19 IgM/IgG Rapid Kit showed specificity of 98.0%

Procedure and Results

- 1 Add 10 uL of the sample (whole blood, serum, or plasma).
- 2 Add 1 drops of Assay Buffer.
- 3 Read the test results after 10~15 minutes.



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