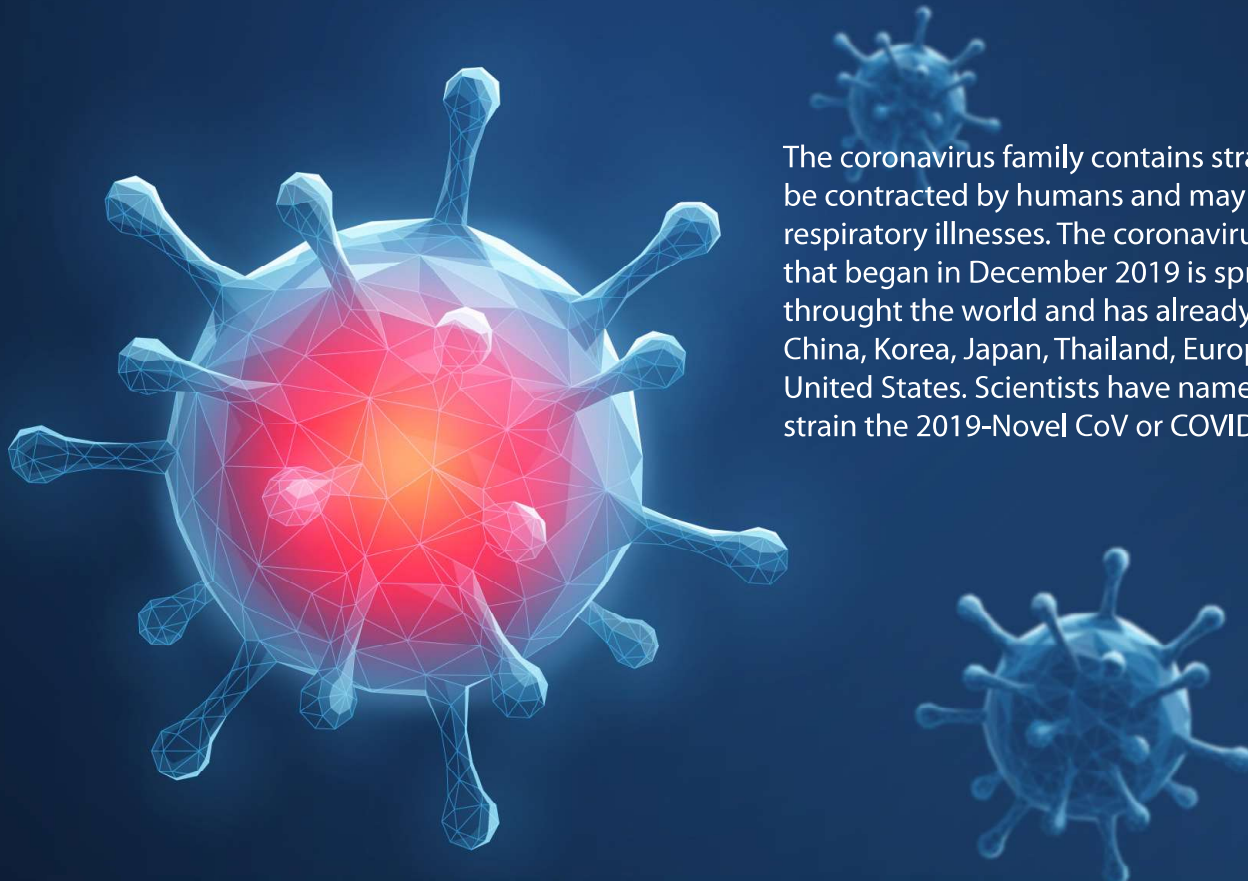# careUS™ COVID-19 IgM/IgG

Highly Specific, can detect Silent Infections

The coronavirus family contains strains that can be contracted by humans and may cause severe respiratory illnesses. The coronavirus outbreak that began in December 2019 is spreading rapidly throught the world and has already impacted China, Korea, Japan, Thailand, Europe, and the United States. Scientists have named the novel strain the 2019-Novel CoV or COVID-19.
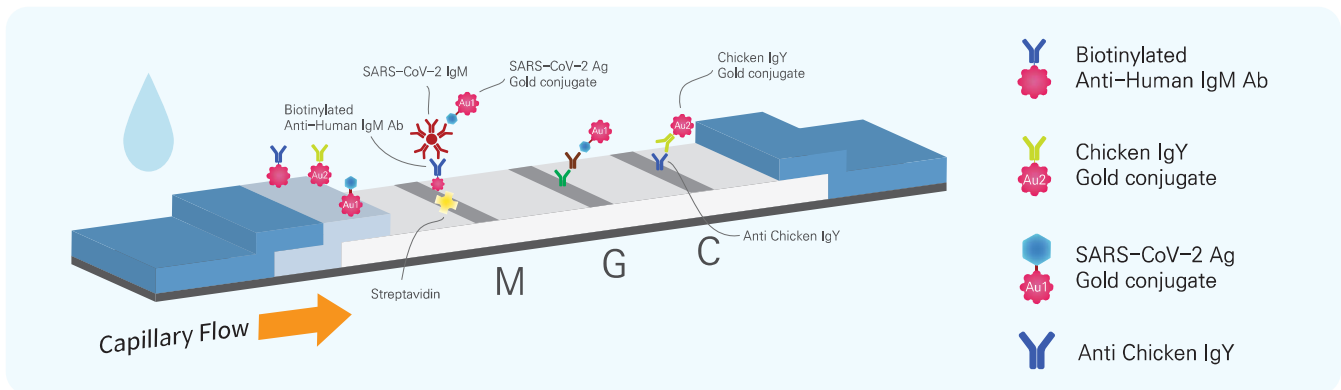
Features

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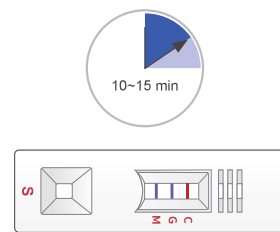- ☑ No special equipment or training required
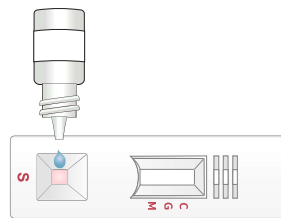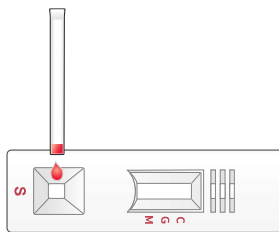
Clinical Features

- ☑ As a supplementary detection indicator for suspected cases with negative nucleic acid detection, or in conjunction with PCR in diagnosis of suspected cases.

WELLS BIO

Test method   Inmuno chromatography using colloidal gold

- SARS-CoV-2 IgM
- SARS-CoV-2 Ag Gold conjugate
- Chicken IgY Gold conjugate
- Biotinylated Anti-Human IgM Ab
- Streptavidin
- Anti Chicken IgY
- M   G   C
- Capillary Flow

- Biotinylated Anti-Human IgM Ab
- Chicken IgY Gold conjugate
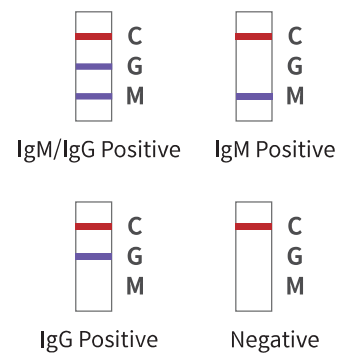- SARS-CoV-2 Ag Gold conjugate
- Anti Chicken IgY

Procedure

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.

10~15 min

Results

IgM/IgG Positive

IgM Positive

IgG Positive

Negative

Clinical Performance

- The clinical performance of careUS™ COVID-19 IgM/IgG was evaluated using retrospectively collected SARS-CoV-2 samples.
- A total of 47 positive and 50 negative specimens were collected from subjects and confirmed by commercially available SARS-CoV-2 RT-PCR as a comparator method.
- The clinical performance of the careUS™ COVID-19 IgM/IgG was compared to the comparator method.

careUS™ COVID-19 IgM/IgG kit		Comparator (RT-PCR)		
		Positive	Negative	Total
Positive	IgG+/IgM+	35	0	35
	IgG+/IgM-	6	0	6
	IgG-/IgM+	3	1	4
Negative	IgG-/IgM-	3	49	52
Subtotal		47	50	97
Positive Percent Agreement (PPA)		93.6% (95% CI: 82.8% – 97.8%)		
Negative Percent Agreement (NPA)		98.0% (95% CI: 89.5% – 99.6%)		

Order Information

Cat. No.	RCO-M02582
Package Unit	25 tests/kit
Kit Component	Test cassette Disposable capillary pipette Assay buffer vial Instructions for use