RapidFor™

INSTRUCTION FOR USE
RapidFor™ SARS-CoV-2 IgG/IgM Test Kit
Catalog Number: VSCD01
For detection of IgG and IgM antibodies against SARS-CoV-2 Detection in Whole Blood/Serum/Plasma

FOR IN VITRO DIAGNOSTIC USE
This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use. It can detect antibodies after vaccination.

INTENDED USE
RapidFor™ SARS-CoV-2 IgG/IgM Test is a colloidal gold enhanced, rapid immunoassay for the qualitative detection of SARS-CoV-2 IgG and IgM antibody in serum, plasma and whole blood samples from patients with suspected SARS-CoV-2 infection.

PRINCIPLE OF THE TEST
The SARS-CoV-2 IgG/IgM Test is a Colloidal gold enhanced capture immunoassay for the qualitative determination of SARS-CoV-2 IgG and IgM antibody in human serum, plasma, and whole blood samples. The product is pre-embedded with recombinant SARS-CoV-2 antigen and rabbit antibody on the nitrocellulose membrane, and coated with anti-human IgM, anti-human IgG and goat anti-rabbit antibody respectively on the T1 line, T2 line and C line on the nitrocellulose membrane. When a positive sample is tested, the SARS-CoV-2 IgM and/or IgG antibody combines with the colloidal gold labeled SARS-CoV-2 antigen to form a complex. Under the action of chromatography, the complex flows along the membrane, when it passes T1 line and/or T2 line it combines with the anti-human IgM and/or IgG to form a colloidal gold complex to show color, and the gold colloidal labeled rabbit antibody combines with Goat anti-rabbit antibody at C lint to show color. Negative samples only show color on C line.

MATERIALS AND COMPONENTS

COMPONENT	1 Test /box	25 Tests /box
Test Device	1 Test cassette (1Test/pouch x 1 pouch)	25 Test cassettes (1 Test/pouch x 25 pouches)
Buffer	1 single-use bottle, (1 mL/vial x 1 bottle)	25 single-use bottles, (1 mL/vial x 25 bottles)
Disposable Dropper	1 sterile, single use Disposable dropper	25 sterile, single use Disposable dropper
Lancet	1 sterile, single use lancet	25 sterile, single use lancet
Packing Insert	1 instruction for use	1 instruction for use

Note: The component in different batches of the kit cannot be mixed.

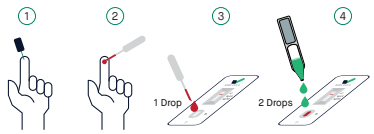
Active components of the test cassette
Reagents
For the test and control lines
mAb anti-human-IgG antibody: 0.50±0.01 μg
mAb anti-human-IgM antibody: 0.90±0.01 μg
mAb anti-chicken IgY: 0.40 ±0.01 μg

For the conjugation pad:
Gold-conjugated SARS-CoV-2 nucleocapsid protein: 0.6 μg ±0.01 μg
Gold-conjugated SARS-CoV-2-S1 protein: 0.92 μg ±0.01 μg
Gold-conjugated SARS-CoV-2-RBD protein: 0.75 μg ±0.01 μg
Purified chicken IgY gold conjugate: 1 μg ±0.01 μg

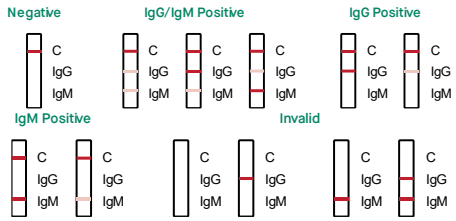
STORAGE AND STABILITY
·Storage: Store in a dry place at 2-30°C
·Shelf life: 24 months.
·The test device should be used as soon as possible after being removed from the aluminum foil bag.
·MFD date and EXP dates are marked on aluminum foil bag.

SPECIMEN REQUIEMENTS
1.It is suitable for serum, plasma, or whole blood samples. The commonly used anticoagulants (heparin, EDTA or sodium citrate) have no effect on the results of this kit.
2.Samples should be collected according to routine clinical methods and avoid hemolysis.
3.If serum or plasma specimens are to be tested in 5 days, they should be refrigerated at 2℃-8℃. Storage at -20℃ should not exceed 3 months. For long time storage, they should be -70°C cryopreservation and avoid repeated freezing and thawing (no more than 3 times).
4.Whole blood samples can be stored at 2"C"8"C kept in refrigerator for 3 days with no cryopreservation.
5.Restore the sample to room temperature before test.
6.Obvious hemolysis, lipohemia and jaundice samples should not be used.
7.Transportation of the samples should be sealed ice cup with ice or sealed foam box with ice.

TEST PROCEDURE
1.Clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused specimen collection disposable dropper to collect the drop of blood.
3.Open the aluminum foil bag, take out the test card, and lay it flat on a flat operating table and number it.
4.Add 1 drop (10 μL) of specimen (whole blood/serum/plasma) to the sample well of the test card using the plastic dropper provided according to the figure.
5.Then add 2 drops (80 μL) of sample diluent to the sample well.



RESULT INTERPRETATION



LIMITATIONS
1.The test results of this product cannot be used as a basis for diagnosis. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions, and further clinical data.
2.In the early stage of infection, the test result may be negative because the SARS-CoV-2 antibody or low antibody level has not yet appeared in the sample.
3.Due to the limitation of the detection method, the negative test result of this reagent cannot exclude the possibility of infection.
4.This reagent can only qualitatively detect SARS-Cov-2 antibodies in human serum, plasma, and whole blood samples. It cannot determine the certain antibody content in the samples.

PERFORMANCE CHARACTERISTIC
RapidFor™ SARS-CoV-2 IgG/IgM Test Kit performance characteristics have been determined by using clinical samples. The ELISA results have been used for comparison and the data which is shown below is determined.

SARS-CoV-2 IgM	ELISA RESULT +	ELISA RESULT -	TOTAL
RapidFor™ SARS-CoV-2 IgG/IgM Test	277	3	280
	5	336	341
Total	282	339	621
Sensitivity: 277/(277+5) = %98.23			
Specificity: 336/(336+3) = %99.12			
Total Coincidence Rate: (277+336)/621 =%98.71			

SARS-CoV-2 IgG	ELISA RESULT +	ELISA RESULT -	TOTAL
RapidFor™ SARS-CoV-2 IgG/IgM Test	290	2	292
	6	315	321
Total	296	317	613
Sensitivity: 290/(290+6) = %97.97			
Specificity: 307/(307+6) = %99.37			
Total Coincidence Rate: (290+315)/613 =%98.69			

Cross-Reactivity
Cross-reactivity of the RapidFor™ SARS-CoV-2 IgG/IgM Test was evaluated using serum samples which contain antibodies to the pathogens listed below. Different pathogens were tested, and no false positives were found with the following.

Sample Categories	Sample No.
Influenza A virus IgG	3
Influenza B virus IgG	3
Respiratory syncytial virus IgG	3
Adenovirus IgG	3
Rhinovirus IgG	3
Human metapneumovirus IgG	3
Mycoplasma pneumoniae IgG	3
Chlamydia pneumoniae IgG	3
HCV IgG	3
Haemophilus influenza IgG	3
HBV core antibody IgG	3
Anti-Flu A IgG	3
Anti-Flu B IgG	3
Anti-Rhinovirus IgG	3
Anti-HCV IgG	3
Anti-HBV IgG	3
Anti-Respiratory Syncytial virus IgG	3
Anti-Haemophilus Influenzae IgG	3
Human coronavirus panel IgG	3
EB Virus Antibody IgG	3
HIV-1 and HIV-2 IgG	3
Parainfluenza virus 1-4 IgG	3
Enterovirus IgG	3
Streptococcus pneumoniae IgG	3
Mycobacterium tuberculosis IgG	3
Influenza A virus IgM	3
Influenza B virus IgM	3
Respiratory syncytial virus IgM	3
Adenovirus IgM	3
Rhinovirus IgM	3
Human metapneumovirus IgM	3
Mycoplasma pneumoniae IgM	3
Chlamydia pneumoniae IgM	3
HCV IgM	3
Haemophilus influenza IgM	3
Bacterial pneumonia	3
Haemophilus Influenza IgM	3
HBV core antibody IgM	3
Antinuclear antibodies (ANA)	3
Anti-Flu A IgM	3
Anti-Flu B IgM	3
Anti-HKU1 (Beta coronavirus)	3
Anti-OC43 (Beta coronavirus)	3
Anti-NL63 (Alpha coronavirus)	3
Anti-229E (Alpha coronavirus)	3
Anti-Rhinovirus IgM	3
Anti-HCV IgM	3
Anti-HBV IgM	3
Anti-Respiratory Syncytial virus IgM	3
Anti-Haemophilus Influenzae IgM	3
Human coronavirus panel IgM	3
EB Virus Antibody IgM	3
HIV-1 and HIV-2 IgM	3
Parainfluenza virus 1-4 IgM	3
Enterovirus IgM	3
Streptococcus pneumoniae IgM	3
Mycobacterium tuberculosis IgM	3

Interference;
SARS-CoV-2 antibody positive serum samples and SARS-CoV-2 antibody negative serum samples investigated with one of the following substances to added with specified concentrations in multiple replicates. No false Positives or false negatives were found with the following:

Name of Substance	Concentration
Ascorbic acid	40 mg/dL
Hemoglobin	8 mg/mL
Albumin	2000 mg/dL
Triglyceride	15 mg/mL
Bilirubin Conjugated	0.3 mg/mL
Human Anti-mouse	780 ng/mL
Bilirubin Unconjugated	0.4 mg/mL
Cholesterol	5 mg/mL
Rheumatoid Factor	2000 IU/mL
Histamine hydrochloride	4 mg/L
Antibody (HAMA) Human Serum Albumin	50 mg/L
Levofloxacin	200 mg/L
α- IFN	200 mg/L
Abidol	50 mg/L
Tobramycin	10 mg/L
Ribavirin	40 mg/L
Ceftriaxone	420 mg/L
Meropenem	210 mg/L

REFERENCES

[1]Bedford J, Enria D, Giesecke J, et at. COVID-19: towards controlling of a pandemic[J]. Lancet,2020.
[2]Andersen K G, Rambaut A, Lipkin W I, et at. The proximal origin of SARS-CoV-2[J]. Nature Medicine,2020.
[3]Guan W, Ni Z, Hu Y, et at. Clinical Characteristics of Coronavirus Disease 2019 in China[J]. The New England journal of medicine,2020.
[4]J Li Z, Yi Y, Luo X, et at. Development and Clinical Application of a Rapid IgM IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis[J]. Journal of Medical Virology,2020.
[5]Xie X, Zhong Z, Zhao W, et al. Chest CT for Typical 2019-nCoV Pneumonia: Relationship to Negative RT-PCR Testing[J]. Radiology,2020:200343.

INDEX OF SYMBOL

	Consult instruction for use
2℃ 30℃	Store at 2℃ ~ 30℃
	Expiry date
	Manufacturer
LOT	Lot Number
	For single use only
REF	Catalog Number
	Keep away from sunlight
Σ	Number of Tests
IVD	In-vitro diagnostic medical device
	Do not use if the package is damaged
	Biohazard
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

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Date of issue: 29.09.2021