RapidFor™

INSTRUCTION FOR USE
SARS-CoV-2 NAb Test (FIA)
Catalog Number: VSCD04
For detection of Neutralizing antibodies against SARS-CoV-2 Vaccine 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.

INTENDED USE
SARS-CoV-2 NAb Test (FIA) is a colloidal gold enhanced, rapid immunoassay for the qualitative detection of **vaccine-induced seropositivity** in serum, plasma, and whole blood samples from patients who vaccinated against SARS-CoV-2 virus. This product is for in vitro use only to detect the antibodies against COVID-19 vaccines. The test kit should be complied with the relevant requirements of the "Pneumonitis Diagnosis and Treatment Scheme for SARS-CoV-2" and "Pneumonitis Prevention and Control Scheme for SARS-CoV-2 " in use. The SARS-CoV-2 is a new type of coronavirus belonging to the genus §. It has a capsule, and its particles are round or oval, often polymorphous, with a diameter of 60-140 nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). In vitro isolation and culture, SARS- CoV-2 can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to isolate and culture in Vero E6 and Huh-7 cell lines.

PRINCIPLE OF THE PROCEDURE
The SARS-CoV-2 NAb Test (FIA) is a colloidal gold enhanced capture immunoassay for the qualitative determination of SARS-CoV-2 IgG against Covid-19 vaccine 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 anti-human IgG and goat anti-rabbit antibody respectively on the T1 line, and C line on the nitrocellulose membrane. When a positive sample is tested, the SARS-CoV-2 IgG antibody combines with the colloidal gold labeled SARS-CoV-2 antigen against vaccine to form a complex. Under the action of chromatography, the complex flows along the membrane, when it passes T1 line, it combines with the anti-human 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.

REAGENTS AND MATERIALS SUPPLIED
Materials provided with the test kits

Component	25 Tests/box
Test Device	25 Test cassettes (1 Test/pouch x 25 pouches)
Buffer	25 single-use bottles, each with 4 ml/vial extraction buffers
Dropper	25 single-use disposables droppers
Lancet	25 single-use lancets
ID Chip	1 ID Chip
Packing Insert	1 instruction for use

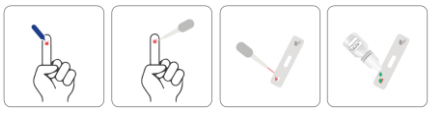
Note: The components in different batches of the kit cannot be mixed.

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℃~8℃ 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

Sample Processing:
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.



6.Turn on the device.
7.Place the ID Chip that stated place.
8. Press "Read ID Chip" part on the screen of the device.

9.Test operation:
Standard testing:
After the sample is added, insert the test card into the instrument and click "start test". The instrument automatically counts the time. After the reaction countdown of 10 minutes is over, the instrument automatically performs the test, and records, reads and prints the test results.
Quick test:
After adding the sample, time 10 minutes with a timer, no more than 15 minutes. When the time is up, insert the test card into the instrument, and click "Start Test". The instrument automatically performs the test, and records, reads, and prints the test results. If the test card fails to be tested in time within 10-15 minutes, it will be deemed as invalid test, and the sample need to be retested with a new test card.

Result Interpretation
This product can only perform qualitative analysis on the detection object. The applicable instrument automatically determines the positive or negative of the sample according to the comparison between the detection value of the detection line and the positive reference value, and directly outputs the qualitative result.
•**Positive:** indicates that both the detection line and the control line detect a fluorescent signal. On the device screen, the antibody level is seen with numerical value.
•**Negative:** indicates that the fluorescent signal is detected on the control line. Results of negativity seen as "Negative" on the device screen.
•**Invalid:** indicates that no fluorescent signal is detected or only the fluorescent signal is detected on the detection line, the interpretation is invalid, and the sample should be re-tested as required.

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 vaccination, the test result may be negative because the SARS-CoV-2 antibody or low antibody level has not yet appeared in the sample.
3.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
SARS-CoV-2 NAb Test (FIA) 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 NAb Test (FIA)	ELISA RESULT +	ELISA RESULT -	TOTAL
SARS-CoV-2 NAb Test (FIA)	179	3	182
	5	298	303
Total	184	301	485

Sensitivity; 179/ (184) = %97.2,
Specificity; 298/ (301) = %99.0,
Total coincidence rate; (179+298)/485 = %98.35

Cross-Reactivity
Cross-reactivity of the SARS-CoV-2 NAb Test (FIA) was evaluated using serum samples which contain antibodies to the pathogens listed below. 24 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

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INDEX OF SYMBOL

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

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