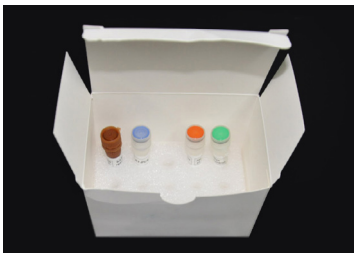
inveox®

SARS-CoV-2 Nucleic Acid Test Kit

(Multiple Fluorescence PCR Method)



Intended Use

SARS-CoV-2 Nucleic Acid Test Kit is a real-time polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper and lower respiratory tract specimens.

Main Components

Kit components	25 assays/Kit	50 assays/Kit	100 assays/Kit
SARS-CoV-2 reaction fluid	475μL/tube × 1	950μL/tube × 1	950μL/tube × 2
RT-PCR enzyme	25μL/tube × 1	50μL/tube × 1	100μL/tube × 1
SARS-CoV-2 positive quality control	50μL/tube × 1	100μL/tube × 1	200μL/tube × 1
Negative quality control	50μL/tube × 1	100μL/tube × 1	200μL/tube × 1

NOTE: The components of kits with different batch numbers are not interchangeable.

Reagents required but not provided:

1. Nucleic acid extraction kit.
2. Dedicated PCR reaction tubes (normally included with GNM-C7-8 Real-time Fluorescent Quantitative PCR Analyzer).

Compatibility

Compatible with ABI fluorescent PCR platforms, such as ABI7500, ABI7500 Fast, ABI7900, ViiATM7, QuantStudio Dx, QuantStudio6 Flex and QuantStudio7 Flex; Roche fluorescent PCR platforms, such as LightCycler480 and Cobas Z480; Shanghai Hongshi fluorescent PCR platforms, such as SLAN-96P, SLAN-48P and SLAN-96S; Agilent fluorescence PCR platforms, such as MX3000P and MX3005P; Bio-rad fluorescence PCR platforms, such as CFX96 and IQ5; GNM-C7-8 Real-Time Fluorescent Quantitative PCR Analyzer.

Test Principle

The kit uses SARS-CoV-2 ORF1ab and the specific conserved sequence of nucleocapsid protein N gene as target regions. Its dual-target gene detection primer probe combines multiplex PCR-fluorescent probe technology with fast one-step RT-PCR technology. Detection of the virus is then completed with the use of a high-efficiency RT-PCR reaction system (not included). Afterwards, the results can be determined by analyzing the cycle threshold (Ct) of each channel.

Instructions for use

Oropharyngeal swabs	Simultaneously wipe the bilateral pharyngeal tonsils and the posterior pharyngeal wall with a plastic rod swab with a polypropylene fiber head, immerse the swab head in a tube containing 3mL (0.1 oz) of sampling solution, discard the tail, and tighten the tube cap.
Nasopharyngeal swabs	Insert a plastic rod swab with a polypropylene fiber head in the nasal passage to reach the nasopalatine duct gently, let it stay for a while and slowly rotate it to exit. Immerse the swab mentioned above in the same tube containing 3mL (0.1 oz) of sampling solution, discard the tail, and tighten the tube cap.
Sputum	Collect the sputum coughed up in a 50mL (1.7 oz) screw-on plastic tube containing 3mL (0.1 oz) of sampling solution

Note: Plastic rod swab and container for sputum sample not included in kit

Specimen preservation	Specimens for virus isolation and nucleic acid detection shall be tested as soon as possible; specimens that can be tested within 24h can be stored at 4 °C (39.2 °F); specimens that cannot be tested within 24h shall be stored at -70 °C (-94 °F) or below (if there is no preservation condition of -70 °C (-94 °F), temporarily store it in a refrigerator at -20 °C (-4 °F)); a special library or cabinet shall be set up to preserve specimens separately; repeated freeze-thaw cycles shall be avoided during transport of specimens.
Quantity	25 tests per kit; 50 tests per kit; 100 tests per kit
Storage Conditions	The kit shall be stored in a dark place at -20±5 °C (-4±9 °F). Repeated freezing-thawing should be avoided (frozen-thaw repetitions shall not exceed 4 times).
Validity/expiration	Please check product label for validity and expiration

Precautions

1. Please read the entire Instructions carefully before using the kit.
2. This product does not contain nucleic acid extraction reagent, which needs to be prepared by the user. Please refer to [Main Components] for details.
3. The kit can be transported in a foam box with dry ice (or a low temperature ice bag).
4. Please strictly follow the management practices of genetic amplification testing laboratories as issued by the industrial administrative department in charge.
5. This kit is an in vitro detection reagent, and the operating personnel must be professionally trained.
6. The entire detection process shall be strictly conducted in three areas, i.e., Reagent Preparation Area, Specimen Preparation Area and Amplification Area. The instruments, equipment, consumables and work clothes used in each area shall be independent and dedicated. The workbench shall be cleaned immediately after the experiment and be disinfected.
7. Please use disposable dedicated centrifuge tubes, calibrated pipettes, tips with filter element, as well as disposable gloves that do not contain fluorescent materials. Gloves must be replaced frequently.
8. The components in the kit shall be used within the validity period. Do not mix reagents of different batches.
9. All reagents must be thawed completely, mixed well and centrifuged at 6,000rpm for a few seconds before use.
10. Instruments and equipment, such as operating tables, pipettes, centrifuges and PCR analyzer, shall be disinfected frequently with 10% sodium hypochlorite or 75% alcohol, UV or ozone.
11. Try to avoid air bubbles in the reaction tube. The tube cap must be tightened.
12. After the amplification is completed, take out the reaction tube, seal it in a special plastic bag, and discard it at the designated place.
13. The test specimens involved with this kit are considered to be infectious substances, and any operation and processing must meet the relevant requirements of General Biosafety Standard for Microbiological and Biomedical Laboratories and Medical Waste Management Regulations released by the Ministry of Health of the People's Republic of China.
14. Test kit for professional use only.

Limitations of Test Method

The test results with the kit are for clinical reference only. For confirmed cases, please combine clinical symptoms and other test methods.
Negative results also cannot rule out SARS-CoV-2 infection. Factors that may lead to false negative results must be excluded, including: poor specimen quality, such as respiratory tract specimens at the oropharynx and other parts; specimens collected too early or too late; specimens not properly stored, transported or processed; reasons of the technology itself, such as virus variation, PCR inhibition, etc.

Clinical Trial Results

This kit has been tested in: Tongji Hospital; Tongji Medical College of HUST; Wuhan Wuchang Hospital; Hubei Provincial Center for Disease Control and Prevention … (SARS-CoV-2 was first identified in 2019 at Wuhan City, Hubei Province, China)

To place an order, please get in touch via email: sampling@inveox.com

Due to high demand and the need to integrate and optimize various supply chains,
the delivered product may vary in appearance and packaging from item in this description.

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