SARS-CoV-2 Antigen Rapid Test Kit（Fluorescence immunoassay)
User manual

【Product name】

SARS-CoV-2 Antigen Rapid Test Kit（Fluorescence immunoassay)

【Package specification】

25 Tests/kit

【Intended use】

SARS-CoV-2 Antigen Rapid Test Kit is a lateral flow immunoassay intended for the quantitative detection of the Nucleocapsid antigen from SARS-CoV-2 in nasopharyngeal swabs from individuals who are suspected of SARS-COV-2 by their healthcare provider within the first 7 days of symptom onset, or for screening of individuals without symptoms, or other reasons to suspect SARS-COV-2 infection, if applicable.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with SARS-CoV-2, and confirmed with a molecular assay, if necessary, for patient management.

The SARS-COV-2 Antigen Rapid Test Kit is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.

【Inspection principle】

The SARS-CoV-2 Nucleocapsid proteins Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of SARS-CoV-2 Nucleocapsid proteins. The SARS-CoV-2 Nucleocapsid proteins in the sample was first bound with the conjugated compound of fluorescent labeled SARS-CoV-2 Nucleocapsid proteins monoclonal antibody, then moved and combined with another SARS-CoV-2 Nucleocapsid proteins monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	It is composed of fluorescent pad (coated with fluorescent labeled SARS-CoV-2 Nucleocapsid proteins monoclonal mouse antibody), nitrocellulose membrane (coated with SARS-CoV-2 Nucleocapsid proteins monoclonal mouse antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25（400μL/tube）	Phosphate buffer
Nasal Mid-Turbinate (NMT) swabs	25	Flocking
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.

The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】

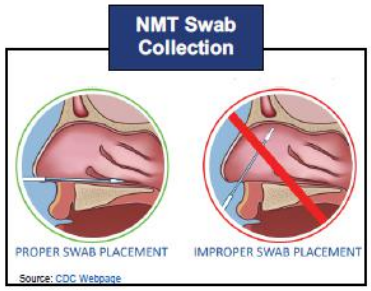
Nir-1000 dry fluorescent immunoassay analyzer produced by WWHS Biotech. Inc.

【Sample requirements】

1. Nasal Mid-Turbinate (NMT) swabs can be used for testing.Venous blood was collected according to routine laboratory methods to avoid hemolysis.
2. Nasal Mid-Turbinate (NMT) swab specimens need to be tested immediately and within 30 minutes of collection..
3. Specimens can be stored at room temperature (15-30 °C) for up to 60 minutes until testing.

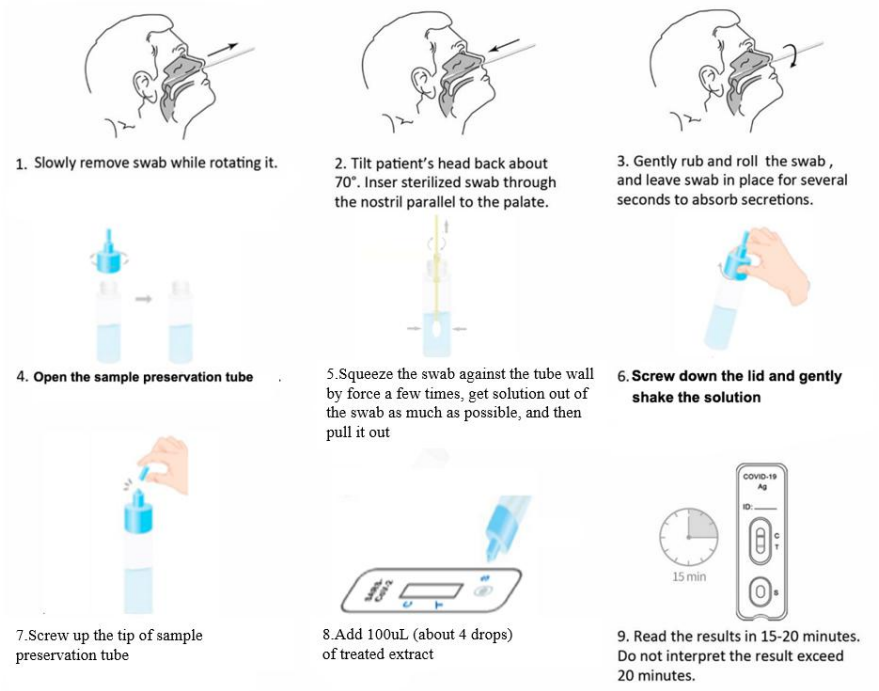
【Test procedure】

- Specimen:



Insert a fresh NMT swab into the patient nostril parallel to the palate. The swab should be inserted less than 1 inch/2cm into the nostril until resistance is met at the turbinate. Rotate the swab several times, then gently remove and repeat the process in the other nostril.

- **Test:**



(1) Start NIR-1000 dry fluoroimmunoassay analyser according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument（Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the information card. The information card is inserted before use, so it is not necessary to calibrate again, and the test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)

(2) Use a fresh NMT swab to collect sample.

(3) Open the tubes and submerge the NMT Swab tip into the Extraction solution.

(4) Squeeze the swab against the tube wall by force 10 times. Withdraw from the tube while rotating and pressing on the tube wall to extract as much liquid as possible and then discard the swab.

(5) Screw down the lid and gently shake the solution, screw up the lip of the tube, and then add 3 drops (squeeze the end of the tube furthest from the dropper head) vertically to the Test Card.

(6) Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 15 minutes after addition of samples, then dispose of used test appropriately.

【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with SARS-CoV-2 Nucleocapsid proteins concentration lower than 0.025ng/ml and higher than 500ng/ml, the detection results are reported as "< 0.025ng/ml" and "> 500ng /ml", respectively.

【Note】

- For in vitro diagnostic use.
- This test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- Proper sample collection, storage and transport are essential for correct results.
- Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots.
- Do not reuse the used test card.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Do not store specimens in viral transport media for specimen storage.

- All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
- Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of SARS-COV-2.
- INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, ½ inch above the swab well, and add drops slowly.
- False Negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.
- Swabs in the kit are approved for use with SARS-COV-2 Ag Card. Do not use other swabs.
- The Extraction Buffer packaged in this kit contains salts, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
- Do not store the swab after specimen collection in the original paper packaging, if storage is needed use a plastic tube with cap.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

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[4] Meyerowitz, E. A.; Richterman, A.; Bogoch, I. I.; Low, N.; Cevik, M. Lancet Infect. Dis. 2021, 21, No. e163.
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【Essential information】

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