BNG SARS-CoV-2 Covid-19 Antigen Rapid Test

Instructions For Use

Professional Use Only

INTENDED USE

SARS-CoV-2 Antigen Rapid Test is intended for the qualitative detection of SARS-CoV-2 Antigen in oropharyngeal swab and nasopharyngeal swab specimens in vitro.

SUMMARY

The SARS-CoV-2 is an enveloped β-coronavirus, circular or elliptical particle diameter of about 60 ~ 140nm, often pleomorphic, obviously different from SARS- CoV and MERS-CoV in genetic characteristics. The main clinical manifestations include fever, fatigue and other systemic symptoms, accompanied by dry cough, dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multi-organ failure, severe acid-base metabolism disorder, and even life-threatening. SARS-CoV-2 has been identified as the main means of transmission through respiratory droplets (sneezing, coughing, etc.) and contact (picking nostril with the hand in contact with the virus, rubbing eyes, etc.).
SARS-CoV-2 is sensitive to ultraviolet ray and heat, and can be inactivated at 56℃ for 30 minutes and by fat soluble solvent such as ethyl ether, 75% ethanol, chlorine disinfectant, peracetic acid and chloroform.

PRINCIPLE

SARS-CoV-2 Antigen Rapid Test employs immuno-lateral chromatography technology for the qualitative detection of antigens. The colloidal gold particles labeled with the anti-SARS-CoV-2 antibody 1 are fixed on the conjugation pad. The anti-SARS-CoV-2 antibody 2 is bound on the “T” test line of nitrocellulose membrane. The Goat Anti-Mouse IgG is bound on the “C” control line of nitrocellulose membrane. When the concentration of SARS-CoV-2 in the specimen is higher than the minimum detection limit, which can conjugate with the anti-SARS-CoV-2 antibody 1 labeled with colloidal gold particles to form a complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the anti-SARS-CoV-2 antibody 2 bound on the test line, forming “Au-Anti-SARS-CoV-2 antibody 1-(SARS-CoV-2) - Anti-SARS-CoV-2 antibody 2 complex. These complexes are deposited to display color as the determination of antigen positive, the rest of anti-SARS-CoV-2 antibody 1 labeled with colloidal gold particles conjugate with the Goat Anti-Mouse IgG and deposit to display color as the determination of quality of the “C” control line. When the concentration of SARS-CoV-2 in the specimen is lower than the minimum detection limit or no SARS-CoV-2, the complexes only deposit and display color in the “C” control line.

KIT COMPONENTS

Cassette type:

1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, Test device: Mouse anti- SARS-CoV-2 monoclonal antibody, Goat Anti-Mouse IgG polyclonal antibody, Nitrocellulose membrane.
Extraction solution: Phosphate Buffer solution (0.01M, pH7.4±0.2)
Extraction tube
Package insert
Disposable swabs (oropharyngeal swab or nasopharyngeal swab)

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

REAGENT STORAGE AND STABILITY

Store the kit at 2-30°C/ 36-86°F, out of direct sunlight, valid for 12 months. Do not freeze the kit. The test device should be used within 60 minutes after opening the foil pouch. For production date and expiration date, please refer to the product label.

SPECIMEN REQUIREMENTS

1. **Specimen collection**

Oropharyngeal swab specimen collection:

The patient should tilt their head slightly upward, open their mouth wide and make a sound of "ah" to expose both pharyngeal tonsils. The disposable swab should be used to cross the tongue base. Wipe both pharyngeal tonsils back and forth with slight force for at least three times, and then wipe the posterior pharyngeal wall up and down for at least three times.

Nasopharyngeal swab specimen collection:

Gently hold the patient's head with one hand, carefully insert the swab into the nostril and slowly go deep along the bottom of the lower nasal passage. When the top of the swab reaches the back wall of the nasopharyngeal cavity, gently rotate it for one round (pause for a moment once reflex cough), and then slowly remove the swab.

2. **Specimen storage**

After treatment, the specimens can be stored at room temperature (15-30℃) for up to 24 hours, at 2-8℃ for up to 72 hours and at -20℃ for up to 36 months. The specimens are allowed to be frozen and thawed for three times.

ASSAY PROCEDURE

Before using the reagent, operate it strictly according to the package insert to ensure the accuracy of the results.

Note:

1.The fresh specimens shall be treated with extraction solution as soon as possible after collection, but no later than 1 hour after collection.

2.Test device, sample and instrument must be at room temperature (15~30℃) during the testing.

SAMPLE PREPARATION

1.Remove one specimen extraction tube from the kit before testing.

2.Label one specimen extraction tube or write specimen number on it.

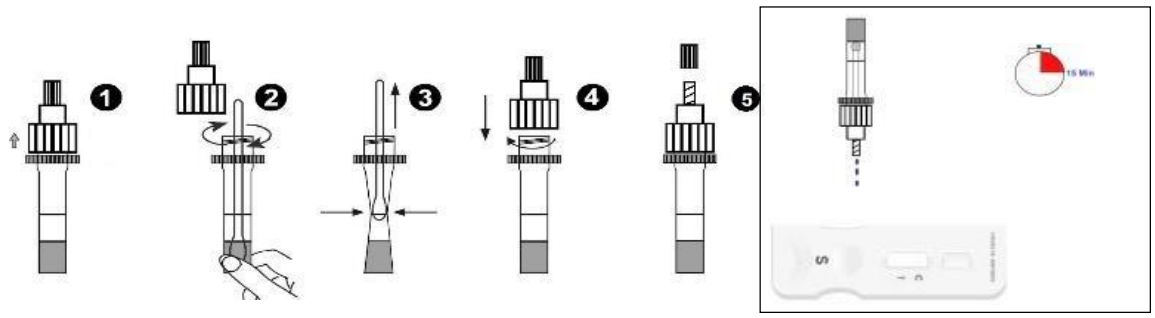
3.Place the labeled specimen extraction tube in a rack in the designated area of the workspace.

4.There is approximately 1 ml of liquid in the extraction solution bottle. Dip the sample stick into this tube.

5. Dip the swab head into the extraction solution in the extraction tube and rotate the swab close to the specimen extraction tube wall for about 10 seconds or 10 times to dissolve the specimens in the solution as much as possible.

6.Squeeze the tip of the swab along the inner wall of the sample extraction tube to keep the liquid in the tube as much as possible, break the swab at the breaking point and lock it

inside the tube. then cap the tube.
7.Tighten the tube cap and wait. then remove the tiny cap of the tube and add 3 drops to the place marked S on the test kit, then wait 15 minutes.



SAMPLE DETECTION

1.Before the detection, the test device and the sample are taken out from the storage condition and balanced to room temperature (15-30℃).
2.Tearing the packaging of the aluminum foil pouch, take out the test device, and place it horizontally on the test table.
3.Vertically invert the specimen extraction tube (the extraction tube with processed specimens), add 2 drops vertically into the sample well of the test device.
4.The test results should be interpreted within 15 to 20 minutes, invalid If more than 30 minutes.
5.Please interpret the result by visual inspection.

POSITIVE VALUE/LIMIT OF DETECTION

Positive value/limit of detection: 1.7×10^{2} TCID50/Ml
Select the confirmed inactivated SARS-CoV-2 medium, (concentration $10^{7.5}$TCID50/mL), use gradient dilution method to find out the virus medium to reach the critical value of the detection. Repeat the action for 20 time and the test result is positive for at least 19 times.

INTERPRETATION OF TEST RESULTS

Positive: Two lines appear. A colored one Line appears in the control area (C) and another colored line appears in the Test area (T) regardless of strength the test line.

Negative: A colored line appears in the Control area (C) and no line appears in the test area (T)

Invalid: The control line is not displayed. Insufficient sample volume or a wrong procedure / handling are the most likely reasons for not Appearance of the control line. Check the procedure and repeat that Test with a new test kit. If the problem persists, exit the use the batch immediately and contact your local dealer.

Note: The color of the test strip will vary with different samples. However, regardless of the color of the test strip, it should be judged as positive result within the specified detection time.

LIMITATION

1.The SARS-CoV-2 Antigen Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 Antigen in oropharyngeal swab and nasopharyngeal swab specimens only.
2.This test kit can only be used for the qualitative detection of SARS-CoV-2 antigens, and can’t determine the quantity of SARS-CoV-2 antigens in samples.

3. If the test result is negative and clinical symptoms persist. It is recommended to repeat sampling or use other testing methods for testing. A negative result cannot preclude the possibility of exposure to or infection with SARS-CoV-2 virus at any time.
4.The test results of the test kits are for clinicians' reference only, and should not be used as the only basis for clinical diagnosis. The clinical management of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses, etc.
5.Due to the limitation of the detection reagent methodology, the limit of detection of this reagent is generally lower than that of nucleic acid reagents. Therefore, the test personnel should pay more attention to the negative results and need to combine other test results to make a comprehensive judgment. It is recommended to use nucleic acid testing or virus isolation and culture identification methods to review negative results which have doubts.
6.Analysis of the possibility of false negative results:

1.Unreasonable specimen collection, transportation and processing, low virus titer in the sample, no fresh sample or freezing and thawing cycling of the sample may lead to false negative results.
2.The mutation of viral gene may lead to changes in antigenic determinants, which lead to negative results.
3.The research on the SARS-CoV-2 has not been completely thorough; the virus may mutate and cause the differences for best sampling time (virus titer peak) and sampling location. Therefore, for the same patient, we can collect samples from multiple locations or follow up for multiple times reduce the possibility of false negative results.

CLINICAL PERFORMANCE

The test results of BNG SARS-CoV-2 Covid-19 Antigen test and the PCR test results are shown in the following table.

		PCR test results		
		Positive (+)	**Negative (-)**	
Test reagent results	**Positive (+)**	159	0	159
	Negative (-)	4	257	261
Total Number		163	257	420

Sensitivity: 97.54%;（95%CI：93.86%~99.04%）**Specificity**:100 %;（95%CI：98.53%~100%）
Total clinical coincidence rate: 99.11%.(95%CI：97.42%~99.70%）

PERFORMANCE CHARACTERISTICS

Using enterprise reference for testing, the results meet the requirements of enterprise reference.

Cross reaction

Name	Concentration	Test result
Influenza B/Y amagata	1.00×10^{2} $TCID_{50}$/mL	Negative
Influenza A H3N2	1.15×10^{2} $TCID_{50}$/mL	Negative
Adenovirus 3	1.24×10^{5} $TCID_{50}$/mL	Negative
Adenovirus 7	1.87×10^{6} $TCID_{50}$/mL	Negative
Human coronavirus 229E	1.00×10^{5} $TCID_{50}$/mL	Negative
Human coronavirus OC43	2.00×10^{6} $TCID_{50}$/mL	Negative

Human coronavirus NL63	2.00×10^6 $TCID_{50}$/mL	Negative
Human Metapneumovirus (hMPV)	1.00×10^5 $TCID_{50}$/mL	Negative
MERS-coronavirus	2.00×10^6 $TCID_{50}$/mL	Negative
Cytomegalovirus	1.00×10^5 $TCID_{50}$/mL	Negative
Enterovirus 71	2.55×10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 1	1.35×10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 2	6.31×10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 3	3.25×10^5 $TCID_{50}$/mL	Negative
Human parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL	Negative
Respiratory syncytial virus	2.00×10^5 $TCID_{50}$/mL	Negative
Rhinovirus 1A	1.26×10^5 $TCID_{50}$/mL	Negative
Chlamydia pneumoniae	1.00×10^5 CFU/mL	Negative
Haemophilus influenzae	1.20×10^6 CFU/mL	Negative
Mycobacterium tuberculosis	1.00×10^5 CFU/mL	Negative
Mycoplasma Pneumoniae	1.00×10^6 CFU/mL	Negative
Neisseria gonorrhoeae	1.00×10^5 CFU/mL	Negative
Pseudomonas aeruginosa	3.70×10^6 CFU/mL	Negative
Staphylococcus aureus	2.20×10^6 CFU/mL	Negative
Streptococcus pneumoniae	1.00×10^6 CFU/mL	Negative
Streptococcus pyogenes	1.28×10^6 CFU/mL	Negative
Streptococcus salivarius	1.00×10^5 CFU/mL	Negative
Staphylococcus epidermidis	1.00×10^6 CFU/mL	Negative
Bordetella pertussis	1.00×10^6 CFU/mL	Negative
Legionella pneumophila	1.00×10^6 CFU/mL	Negative
Pneumocystis jirovecii (PJP)	1.00×10^6 CFU/mL	Negative
Candida albicans	1.00×10^6 CFU/mL	Negative
Pooled human nasal wash – representative of normal respiratory microbial flora	N/A	Negative

Interfering Substance

Interfering substance name	Concentration	Negative interference result	Positive interference result
Mucin	5%	Negative	Positive
Whole blood	5% (V/V)	Negative	Positive
Zanamivir	500ng/mL	Negative	Positive
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Negative	Positive
Naso GEL (NeilMed)	5% v/v	Negative	Positive
CVS Nasal Spray (Cromolyn)	15% v/v	Negative	Positive
Afrin (Oxymetazoline)	15% v/v	Negative	Positive
Zicam	5% v/v	Negative	Positive
Homeopathic (Alkalol)	1:10 dilution	Negative	Positive
Sore Throat Phenol Spray	15% v/v	Negative	Positive
Mupirocin	10 mg/mL	Negative	Positive
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	Negative	Positive
Cepacol Lozenges(benzocaine/menthol)	3 mg/mL	Negative	Positive
Chloroseptic Sore Throat spray (Phenol, Glycerin)	5% v/v	Negative	Positive
Naoacort Allergy 24 hours (Triamcinolone)	15% v/v	Negative	Positive
Tobramycin	4ng/mL	Negative	Positive
Phenylephrine	20µg/mL	Negative	Positive

Crest/Listerine Mouthwash (Eucalyptol, menthol, Methyl Salicylate, Thymol)	5% v/v	Negative	Positive
Flunisolide	0.1mg/mL	Negative	Positive
Sodium chloride	5%	Negative	Positive

Hook effect

Within the concentration of $10^{7.5}$ TCID50/mL for cell culture medium of SARS-CoV-2 antigen, the test results of this product showed no Hook effect.

WARNINGS AND PRECAUTIONS

1.The sample should be tested in the laboratory with certain conditions. All samples and materials in the testing process shall be handled in accordance with the laboratory practice for infectious diseases.
2.The kit shall be stored in strict accordance with the conditions specified in this package insert. Please use it within the validity period.
3.Do not open the sealed pouch until you are ready to perform a test. The kit should be sealed and protected against moisture. If the foil pouch is damaged or damp, stop using it immediately.
4.Specimen collection and detection should be performed accordance with the package insert strictly.

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Do Not Reuse	In Vitro Diagnostic Medical Device
Store at 2-30°C	Consult Instructions For Use
Batch code	Contains sufficient for < n> tests
Use-by Date	away from direct sunlight
Stay dry	Don't use if that Package is damaged
Manufacturer	production date
Authorized representative in the European Community / European Union	Europe approval

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