RAPID SARS-COV-2 ANTIGEN TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF SARS-CoV-2 VIRUS ANTIGEN
IN NASOPHARYNGEAL SWAB SPECIMENS
Catalog Number: 1N40C5

For In Vitro Diagnostic Use Only

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein from SARS-CoV-2 in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset.

Results are for the identification of SARS-CoV-2 nucleocapsid protein. Antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. 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 COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

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

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatographic lateral flow device that employs the principle of double antibody sandwich method. Colloidal gold conjugated anti-SARS-CoV-2 antibodies are dry-immobilized on the test device. When the specimen is added, it migrates by capillary diffusion through the strip to re-hydrate the gold conjugate complexes. If present at or above the limit of detection, SARS-CoV-2 viral antigens will react with the gold conjugate complexes to form particles, which will continue to migrate along the strip until the Test Zone (T) where they are captured by the immobilized anti-SARS-CoV-2 antibodies to form a visible red line. If there are no SARS-CoV-2 viral antigens in the specimen, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until being captured by immobilized antibody in the Control Zone (C) to form a red line, which indicates the validity of the test.

MATERIALS PROVIDED

1. Rapid SARS-CoV-2 Antigen Test Card - 20 UNITS
2. Sterilized swab - 20 UNITS
3. Extraction tube - 20 UNITS & tube rack - 1 UNIT
4. Sample extraction buffer - 2 UNITS (4 mL each)
5. Instructions for use - 1 UNIT

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, specimen collection container, biohazard waste container. personal protection equipment.

STORAGE

1. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
2. Kit contents are stable until the expiration date printed on the outer box based on the proper storage conditions.
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.
4. The collected samples can be stored at 2-8ºC for eight hours. The collected samples can be stored at -20ºC for one month. Test results for collected samples were consistent before and after three freeze-thaw cycles.

PRECAUTIONS

1. For **professional *in vitro*** diagnostic use only.
2. The product is strictly for medical professional use only and not intended for personal use.
3. Do not use the product beyond the expiration date.
4. Do not use the product if the pouch is damaged or the seal is broken.
5. Handle all specimens as potentially infectious.
6. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material.
7. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
8. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.

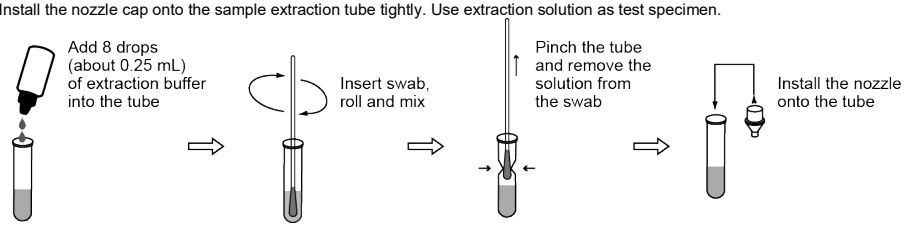
SPECIMEN COLLECTION

Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. Use only the swabs included with the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

SPECIMEN PREPARATION

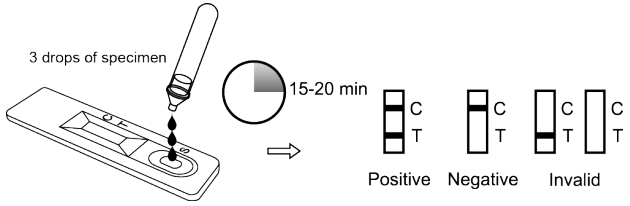
1. Add **8 drops (about 0.25 mL)** of extraction buffer into the extraction tube.
2. Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. **Leave the swab in the extraction buffer for 1 minute**.
3. Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.



PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the card. Once opened, the test card must be used within 1 hour. Label the test card with patient identity.
3. Invert the extraction tube and add **3 drops (about 75 µL)** of test specimen into the specimen well (S) by gently squeezing the extraction tube. The formation of air bubbles in the specimen well (S) must be avoided.
4. Read the results at **15-20 minutes**.

Note: Results after 20 minutes may not be accurate.



INTERPRETATION OF RESULTS

Positive:

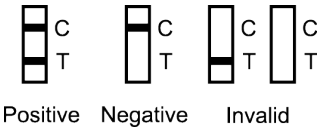
If two colored bands appear within 15-20 minutes with one colored band in the Control Zone (C) and another in the Test Zone (T), the test result is positive and valid. No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive. A positive result does not rule out co-infections with other pathogens.

Negative:

If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative and valid. A negative result does not exclude SARS-CoV-2 viral infection and should be confirmed by molecular diagnostic method if COVID-19 disease is suspected.

Invalid result:

The test result is invalid if there is no colored band in the Control Zone (C) within 15-20 minutes. Repeat the test with a new test device.



QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the regularly use of control materials to validate the reliability of the device. It is recommended that the quality control should be carried out at an interval of 3 months and when the new batch number is used for the first time. Control materials are not provided with this test kit and are available to purchase separately from Xiamen Boson Biotech Co., Ltd. Please contact us for details.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The limit of detection (LoD) for the Rapid SARS-CoV-2 Antigen Test Card was established in an analytical sensitivity study performed with one virus strain. The LoD was confirmed in the following table.

No.	Item	Limit of Detection
1	SARS-CoV-2, Virus	1.3 x10^2 $TCID_{50}$/mL

Cross Reactivity

The cross reactivity of the Rapid SARS-CoV-2 Antigen Test Card was evaluated with a total of 33 microorganisms and other substances. None of the microorganisms and other substances tested in the following table gave a positive result.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0 x 10^6 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.0 x 10^6 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus NL63	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Respiratory syncytial virus	2.0 x 10^6 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus 71	2.0 x 10^6 $TCID_{50}$/mL	Pneumocystis jirovecii (PJP)	2.0x10^6 copies/mL
Human Metapneumovirus (hMPV)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus epidermidis	2.0 x 10^6 CFU/mL
Human coronavirus HKU1	2.0 x 10^6 $TCID_{50}$/mL	Pooled human nasal wash	N/A
Parainfluenza virus 4	2.0 x 10^6 $TCID_{50}$/mL		

The cross reactivity of the Rapid SARS-CoV-2 Antigen Test Card was evaluated with SARS-coronavirus. SARS-coronavirus specimens tested at 2.0 x 10^6 $TCID_{50}$/mL gave a positive result and cross reactivity was observed.

Interference

1. Microorganism

Rapid SARS-CoV-2 Antigen Test Card has tested samples with common microorganisms. The results showed that these microorganisms had no effect on the specificity of the assay up to the listed concentration.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0 x 10^6 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.0 x 10^6 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus NL63	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Respiratory syncytial virus	2.0 x 10^6 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus 71	2.0 x 10^6 $TCID_{50}$/mL	Pneumocystis jirovecii (PJP)	2.0x10^6 copies/mL
Human Metapneumovirus (hMPV)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus epidermidis	2.0 x 10^6 CFU/mL
Human coronavirus HKU1	2.0 x 10^6 $TCID_{50}$/mL	Pooled human nasal wash	N/A
Parainfluenza virus 4	2.0 x 10^6 $TCID_{50}$/mL		

2. Endogenous and Exogenous Substances

Rapid SARS-CoV-2 Antigen Test Card has tested samples with common endogenous and exogenous substances. The results showed that these substances had no effect on the specificity of the assay up to the listed concentration.

Substances	Concentrations	Substances	Concentrations
Whole Blood	1% v/v	Homeopathic (Alkalol)	10% v/v
Mucin	2% w/v	CVS Nasal Drops (Phenylephrine)	15% v/v
Tobramycin	0.0004% w/v	Afrin (Oxymetazoline)	15% v/v
Ricola (Menthol)	0.15% w/v	CVS Nasal Spray (Cromolyn)	15% v/v
Chloraseptic (Benzocaine)	0.15% w/v	Fluticasone Propionate	5% v/v
Mupirocin	0.25% w/v	Zicam	5% w/v
Tamiflu (Oseltamivir Phosphate)	0.5% w/v	Naso GEL (NeilMed)	5% v/v
HAMA	60 ng/mL		

Accuracy

The accuracy of Rapid SARS-CoV-2 Antigen Test Card was established with 236 nasopharyngeal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the accuracy of the Rapid SARS-CoV-2 Antigen Test Card compared to RT-PCR.

		RT-PCR		
		Positive	Negative	Total
Rapid SARS-CoV-2 Antigen Test Card	Positive	30	4	34
	Negative	2	200	202
	Total	32	204	236

The sensitivity was 93.75% (95%CI: 85.36%~99.99%). The specificity was 98.04% (95%CI: 96.14%~99.94%). The accuracy was 97.46% (95%CI: 95.45%~99.47%).

Hook Effect

No hook effect was found when testing different SARS-CoV-2 viral cultures (NR-52284, Italy-INMI1 at 1.02×10^8 $TCID_{50}$/mL; NR-52281, USA-WA1/2020 at 9.55×10^6 $TCID_{50}$/mL; NR-52282, Hong Kong/VM2000106/2020 at 1.15×10^7 $TCID_{50}$/mL) and SARS-CoV-2 recombinant antigens at 3 μg/mL.

LIMITATIONS

1. The test is limited to the qualitative detection of SARS-CoV-2 viral antigen in nasopharyngeal swab specimens. The exact concentration of SARS-CoV-2 viral antigen cannot be determined by this assay.
2. Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results. Improper specimen collection, storage or repeated freezing and thawing of specimens can lead to inaccurate results.
3. A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 disease is suspected.
6. Positive test results do not rule out co-infections with other pathogens.
7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
8. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.
9. The Rapid SARS-CoV-2 Antigen Test Card can detect both viable and non-viable SARS-CoV-2 material. The Rapid SARS-CoV-2 Antigen Test Card for rapid detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
10. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
11. The test was validated with the swab that is included as part of the kit.
12. Specimen stability recommendations are based upon stability data. Users should test specimens as quickly as possible after specimen collection, and within eight hours after specimen collection.
13. The validity of Rapid SARS-CoV-2 Antigen Test Card has not been proven for dentification/confirmation of tissue culture isolates and should not be used in this capacity.
14. The performance of this device has not been assessed in a population vaccinated against COVID-19.
15. Use in conjunction with the testing strategy outlined by public health authorities in your area.
16. Laboratories are required to report all positive results to the appropriate public health authorities.
17. Positive results may occur in cases of infection with SARS-CoV.
18. The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.
19. The test is stable at the following conditions: 8 hours under 15-30°C and a relative humidity of 20-30%; 4 hours under 15-30°C and a relative humidity of 50-60%; 1 hours under 15-30°C and a relative humidity of 80-90%.

REFERENCES

1. Wu C, Liu Y, Yang Y, Zhang P, Zhong W, Wang Y, et al. (February 2020). "Analysis of therapeutic targets for SARS-CoV-2 and discovery of potential drugs by computational methods". Acta Pharmaceutica Sinica B. doi:10.1016.

EXPLANATION FOR SYMBOLS

IVD	*In Vitro* Diagnostics Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Keep Dry	LOT	Batch Number
EC REP	Authorized Representative		Keep away from Sunlight		Manufacturer
	Do not reuse		Do not use if package is damaged	30°C 4°C	Store between 4 ~ 30°C
CE	CE Mark	REF	Catalogue Number		Warning, please refer to the instruction

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