Rapid SARS-CoV-2 Antigen Test Card

FOR THE QUALITATIVE ASSESSMENT OF SARS-CoV-2 VIRUS ANTIGEN IN NASAL SWAB, NASOPHARYNGEAL SWAB OR OROPHARYNGEAL SWAB SPECIMENS

Catalog Number: 8AL10-020

For In Vitro Diagnostic Use Only

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in nasal swabs, nasopharyngeal swabs or oropharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. It is intended for professional use as an aid in diagnosis of SARS-CoV-2 infection.

Rapid SARS-CoV-2 Antigen Test Card detects the SARS-CoV-2 nucleocapsid protein (N protein). Theoretically, genetic SARS-CoV-2 variants with non-nucleocapsid protein mutations do not affect the product performance.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, 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 the 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
2. Sterilized swab
3. Extraction buffer tube
4. Tube holder
5. Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED

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

STORAGE

1. Store the test device at 2 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.

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 laboratory 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.
9. Specimen stability recommendations are based upon stability data. Users should test specimens as quickly as possible after specimen collection, and within two hours after specimen collection. If testing cannot be performed immediately, specimen may be stored at 2-8ºC up to eight hours in case of delay in testing. For long-term storage, specimens can be frozen at -20ºC for 3 months. Avoid repeated freezing/thawing cycles.

SPECIMEN COLLECTION

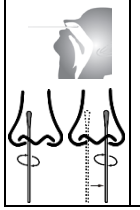
Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. For optimal test performance, use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

Nasopharyngeal swab specimens:

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.

Oropharyngeal swab specimens:

1. The patient's head should be tilted slightly, with mouth open, and the patient should make an "ah" sound, exposing the pharyngeal tonsils on both sides.
2. Holding the swab, wipe the pharyngeal tonsils on both sides with moderate force back and forth at least 3 times. Avoid touching the tongue, teeth and gums.

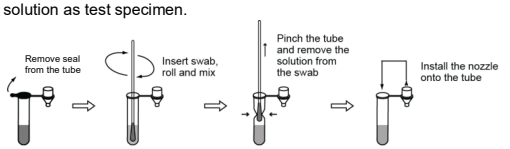


Nasal swab specimens:

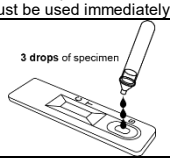
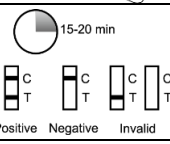
1. Carefully insert the swab into the nostril of the patient. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril.
2. Roll the swab 3-4 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Leave the swab in the nostril for several seconds.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity.

SPECIMEN PREPARATION

1. Remove the seal from the extraction buffer tube.
2. Place the swab with specimen into the extraction buffer tube. Roll the swab three to five (3-5) times. **Leave the swab in the extraction buffer for 1 minute.**
3. Pinch the extraction buffer 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 extraction buffer 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 test card. Once opened, the test card must be used immediately. Label the test card with the patient identity.	
3		Invert the extraction buffer tube and add **3 drops** (about 75 µL) of test specimen into the specimen well (S) by gently squeezing the extraction buffer 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 a molecular diagnostic method if COVID-19 disease is suspected.

INVALID

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 daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

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 and one recombinant nucleocapsid protein. 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
2	SARS-CoV-2, Recombinant nucleocapsid protein	1 ng/mL

Cross Reactivity

The cross reactivity of the Rapid SARS-CoV-2 Antigen Test Card was evaluated with a total of 27 microorganisms. None of the microorganisms 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	2.0 x 10^6 $TCID_{50}$/mL		

Interference

1. Microorganism

The interference of common microorganisms on the performance of the Rapid SARS-CoV-2 Antigen Test Card was evaluated. The results showed that the microorganisms listed in the table below had no effect on the specificity of the assay up to the listed concentration.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0×10^6 $TCID_{50}$/mL	MERS-coronavirus	1.0×10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.0×10^6 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0×10^6 IFU/mL
Human coronavirus NL63	2.0×10^6 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0×10^6 CFU/mL
Parainfluenza virus 1	2.0×10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0×10^6 CFU/mL
Parainfluenza virus 2	2.0×10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0×10^6 CFU/mL
Parainfluenza virus 3	2.0×10^6 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0×10^6 CFU/mL
Enterovirus EV71	2.0×10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0×10^6 CFU/mL
Respiratory syncytial virus	2.0×10^6 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0×10^6 U/mL
Rhinovirus	2.0×10^6 $TCID_{50}$/mL	Haemophilus influenzae	2.0×10^6 CFU/mL
Influenza A virus (H1N1)	2.0×10^6 $TCID_{50}$/mL	Candida albicans	2.0×10^6 CFU/mL
Influenza A virus (H3N2)	2.0×10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0×10^6 CFU/mL
Influenza B virus (Yamagata)	2.0×10^6 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0×10^6 CFU/mL
Influenza B virus (Victoria)	2.0×10^6 $TCID_{50}$/mL	Escherichia coli	2.0×10^6 CFU/mL
Adeno virus	2.0×10^6 $TCID_{50}$/mL		

2. Endogenous Substances

The interference of common endogenous substances on the performance of the Rapid SARS-CoV-2 Antigen Test Card was evaluated. The results showed that the endogenous substances listed in the table below 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		

Clinical Precision

For nasopharyngeal swab specimens:

The clinical precision of the Rapid SARS-CoV-2 Antigen Test Card was established with 566 nasopharyngeal swab specimens collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the clinical precision of the Rapid SARS-CoV-2 Antigen Test Card compared to RT-PCR (Ct value within range 15.98 to >40, Ct cut-off: 35).

		RT-PCR		
		Positive	Negative	Total
Rapid SARS-CoV-2 Antigen Test Card	Positive	98	4	102
	Negative	4	460	464
	Total	102	464	566
Sensitivity		96.08% (95% CI: 92.31% - 99.85%)		
Specificity		99.14% (95% CI: 98.30% - 99.98%)		
Clinical Precision		98.59% (95% CI: 97.61% - 99.56%)		

For oropharyngeal swab specimens:

The clinical precision of the Rapid SARS-CoV-2 Antigen Test Card was established with 231 oropharyngeal swab specimens collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the clinical precision of the Rapid SARS-CoV-2 Antigen Test Card compared to RT-PCR (Ct value within range 19.98 to >40, Ct cut-off: 35).

		RT-PCR		
		Positive	Negative	Total
Rapid SARS-CoV-2 Antigen Test Card	Positive	102	1	103
	Negative	4	124	128
	Total	106	125	231
Sensitivity		96.23% (95% CI: 92.60% - 99.85%)		
Specificity		99.20% (95% CI: 97.64% - 99.99%)		
Clinical Precision		97.84% (95% CI: 95.96% - 99.71%)		

For nasal swab specimens:

The clinical precision of the Rapid SARS-CoV-2 Antigen Test Card was established with 230 nasal swab specimens collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the clinical precision of the Rapid SARS-CoV-2 Antigen Test Card compared to RT-PCR (Ct value within range 18.57 to >40, Ct cut-off: 35).

		RT-PCR		
		Positive	Negative	Total
Rapid SARS-CoV-2 Antigen Test Card	Positive	101	1	102
	Negative	4	124	128
	Total	105	125	230
Sensitivity		96.19% (95% CI: 92.53% - 99.85%)		
Specificity		99.20% (95% CI: 97.64% - 99.99%)		
Clinical Precision		97.83% (95% CI: 95.94% - 99.71%)		

Detection rate of positive samples with different onset days are summarized below:

Onset Days	Number of Samples	Detection Rate
1-3 days	165	161/165, 97.58% (95% CI: 95.23% - 99.92%)
4-7 days	148	140/148, 94.59% (95% CI: 90.95% - 98.24%)

Precision: According to the evaluation method of 5 days × 20 replicates × 3 sites, the precision study of 3 batches of kits showed that Rapid SARS-CoV-2 Antigen Test Card has good repeatability and reproducibility when tested by multiple operators.

Hook Effect Studies: The Rapid SARS-CoV-2 Antigen Test Card did not show hook effect when testing recombinant antigens at a concentration of 3.72 μg/mL and testing viral cultures at concentrations of 1.02×10^8 $TCID_{50}$/mL, 1.15×10^7 $TCID_{50}$/mL and 9.55×10^6 $TCID_{50}$/mL.

LIMITATIONS

1. The test is limited to the qualitative detection of SARS-CoV-2 viral antigen in nasal swab, nasopharyngeal swab or oropharyngeal 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.
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 kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
12. 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.
13. The sensitivity of nasal swab specimens and oropharyngeal swab specimens might be lower than nasopharyngeal swab specimens. It is recommended to use the nasopharyngeal swab specimens.

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

SYMBOL	DEFINITION	SYMBOL	DEFINITION
CE	European Conformity	REF	Catalogue Number
IVD	In Vitro Diagnostics Medical Device		Manufacturer
	Consult Instruction for Use	EC REP	Authorized Representative in the European Community
	Temperature Limitation		Caution, consult accompanying documents
LOT	Lot Number	Σ	Contains sufficient for <n> tests
YYYY-MM-DD	Use by		Do not reuse
STERILE EO	Sterilized using ethylene oxide		

Private Label Manufacturer:
MP Biomedicals Asia Pacific Pte Ltd
2 Pioneer Place, Singapore 627885
Phone: +65 6775 0008
Fax: +65 6775 4536
Email: enquiry_ap@mpbio.com

Original Equipment Manufacturer:
Xiamen Boson Biotech Co., Ltd.
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Phone: +49 (0) 5651 – 921-186
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E-mail: diagnostics@mpbio.com

Sterile swabs:

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CE 0197
EC REP
Luxus Lebenswelt GmbH
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Goodwood Medical Care Ltd.
1-2 Floor, 3-919 Yongzheng Street, Jinzhou District, Dalian, 116100 Liaoning, China

CE 0197
EC REP
CMC Medical Devices & Drugs S.L.
C/HoracioLengoNo18, CP29006,Málaga,Spain

Jiangsu Rongye Technology Co.,LTD
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