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English

COVID-19 (SARS-CoV-2) Antigen Test Kit Instructions for Use

INTENDED USE

The COVID-19 (SARS-CoV-2) Antigen Test Kit is a lateral flow immunoassay designed to qualitatively detect antigens of SARS-CoV-2 (COVID-19)(nucleocapsid protein) in human nasal swab samples . The test is intended as an aid in diagnosis of symptomatic individual meeting respiratory infection for SARS-CoV-2 (within the first 7 days of the onset of symptoms).This kit is designed for home use by laypersons in non-laboratory settings. Individuals aged 15 years and older may perform the test independently. For users under 15 years of age, the test should be conducted or supervised by an adult.Test results of this kit are for clinical reference only. It is recommended that a comprehensive analysis of the disease be conducted based on clinical manifestations of patients and other laboratory tests.

PRINCIPLE

The COVID-19 (SARS-CoV-2) Antigen Test Kit is a lateral flow immunoassay based on the principle of the double antibody sandwich technique. A monoclonal COVID-19 antibody conjugated with colored microparticles and sprayed onto the conjugation pad is used as a detector . During the test, the COVID-19 antigen conjugated with colored microparticles , creating an antigen-antibody labeled complex .This complex migrates on the membrane by capillary action up to the Test line where it is captured by the pre-coated monoclonal COVID-19 antibody. A colored test line will be visible in the result window if COVID-19 is present in the sample . The absence of the T line indicates a negative result .The control line (C) is for procedural control and should appear whenever the test procedure is being performed properly.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use after the expiration date.
3. Perform the test at room temperature 15 to 30°C.
4. The test cassette should remain in the sealed pouch until use.
5. Please read all information in this leaflet before performing the test.
6. Components from different lots must not be mixed or used together.
7. Positive result cannot necessarily determine whether a person is infectious.
8. If you have physical or visual impairments, ask a caregiver to assist with sampling and testing

STORAGE AND STABILITY

Store the test kit in the original packaging at 2°C–30°C. Do not freeze. Test kit contents remain stable until the expiration date printed on the outer packaging.
After opening the pouch, the test should be used within one hour. Prolonged contact with hot and humid environment will cause the product to deteriorate.

LIMITATIONS

1. A negative result does not rule out infection with another type of respiratory virus.
2. The test can only be used once.
3. The performance of COVID-19 (SARS-CoV-2) Antigen Test Kit was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
4. In particular, false negative results may occur if the testing is not performed within the first 7 days of the onset of COVID-19 or if the antigen level in the sample is below the detection limit.
5. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
6. Recommend repeat testing within 1-3 days if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
7. Negative results may not mean that a person is not infectious and if symptoms persist, please seek medical advice.

SAFETY INFORMATION

1. Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.
2. Test kit solutions should only be used as directed; do not ingest; do not dip the swab into the provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use.
3. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical center. that a person is not infectious and if symptoms persist, please seek medical advice.

CLINICAL PERFORMANCE

The clinical performance of the COVID-19 (SARS-CoV-2) Antigen Test Kit for professional use has been evaluated against RT-PCR , and the results are as follows:
Clinical sensitivity =99.08%(216/218 known confirmed Positives,95%CI*96.72% to 99.75%)
Clinical specificity =99.31%(434/437 known confirmed Negatives,95%CI*98.00% to 99.77%)
*:95%confidence interval.

USABILITY STUDY RESULTS

The usability study was conducted with lay persons who performed the test and interpreted the result. The test procedure and obtain consistent test results with professionals. The results were compared to an RT-PCR with a sensitivity of 100% (42/42) and specificity of 100% (82/82).

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The limit of detection of the test was confirmed to be$1.0x10^2$ $TCID_{50}$/mL.

FREQUENTLY ASKED QUESTIONS

1.Will other diseases affect the result?
The potential cross-reactivity of the following pathogens was evaluated with SARS-CoV-2 negative and positive samples using the COVID-19 (SARS-CoV-2) Antigen Test Kit. No cross-reactivity results was observed.

Cross bacterial/virus strains	Concentration	Cross bacterial/virus strains	Concentration
SARS-CoV	1.0×10^6 copies/mL	Adenovirus 5	1.8×10^5 $TCID_{50}$/mL
Human coronavirus NI63	2.0×10^5 $TCID_{50}$/mL	Adenovirus 7	1.38×10^7 $TCID_{50}$/mL
Human coronavirus HKU1	8.87×10^6 copies/mL	Adenovirus 55	1.0×10^5 $TCID_{50}$/mL
Human coronavirus Oc43	2.0×10^5 $TCID_{50}$/mL	Enterovirus Ev70	2.0×10^5 $TCID_{50}$/mL
Human coronavirus229E	2.0×10^5 $TCID_{50}$/mL	Bordetella pertussis	5.2×10^7 cfu/mL
MERS-CoV	1.0×10^6 copies/mL	Chlamydia pneumoniae	1.0×10^5 $TCID_{50}$/mL
Respiratory syncytial virus Type A	1.2×10^5 $TCID_{50}$/mL	Coxsackievirus Ca16e	3.77×10^4 pfu/mL
Respiratory syncytial virus Type B	2.82×10^7 $TCID_{50}$/mL	Coxsackievirus B5	2.0×10^5 $TCID_{50}$/mL
Parainfluenzavirus 1	1.2×10^5 $TCID_{50}$/mL	CoxsackievirusA24	2.0×10^5 $TCID_{50}$/mL
Parainfluenzavirus 2	3.55×10^5 pfu/mL	Candida albicans	2.6×10^6 cfu/mL
Parainfluenzavirus 3	3.2×10^5 $TCID_{50}$/mL	Human MetapneumovirusA2	1.6×10^5 $TCID_{50}$/mL
Parainfluenzavirus 4	1.8×10^6 $TCID_{50}$/mL	Legionella pneumophila	1.8×10^7 cfu/mL
Seasonal influenza A H1N1virus	6.21×10^7 $TCID_{50}$/mL	Mycobacterium tuberculosis	1.0×10^5 cfu/mL
InfluenzaA H3N2virus	4.52×10^7 $TCID_{50}$/mL	Mycoplasma pneumoniae	7.66×10^7 $TCID_{50}$/mL
InfluenzaA H5N1virus	4.71×10^7 $TCID_{50}$/mL	Pneumocystis jiroveci	1.6×10^7 cfu/mL
Influenza B Yamagata	3.65×10^7 $TCID_{50}$/mL	Streptococcus pneumoniae	1.8×10^6 cfu/mL
Influenza B Victoria	4.88×10^7 $TCID_{50}$/mL	Streptococcus pyogenes	2.3×10^7 cfu/mL
Haemophilus influenzae	1.0×10^7 cfu/mL	RhinovirusA2	1.6×10^5 $TCID_{50}$/mL
Adenovirus 1	1.2×10^6 $TCID_{50}$/mL	Rhinovirus B52	1.5×10^5 $TCID_{50}$/mL
Adenovirus 2	2.8×10^5 $TCID_{50}$/mL	Staphylococcus aureus	3.0×10^6 cfu/mL
Adenovirus 3	1.8×10^5 $TCID_{50}$/mL	Staphylococcus epidermidis	3.6×10^7 cfu/mL
Adenovirus 4	1.4×10^5 $TCID_{50}$/mL	SARS-CoV-1	5.6×10^6 $TCID_{50}$/mL

2. Does these substances interfere with the test ?
The following substances were spiked into samples and tested with the COVID-19 (SARS-CoV-2) Antigen Test Kit. No interference results was observed.

Interfering substances	Concentration	Interfering substances	Concentration
Mucin	2mg/mL	Peramivir	6mg/mL
Human blood (EDTA anticoagulated)	4% (v/v)	Lopinavir	160mg/mL
Beclomethasone dipropionate nasal aerosol	15% (v/v)	Ritonavir	160mg/mL
Physiological seawater nasal spray	15% (v/v)	Levofloxacin	5mg/mL
Triamcinolone acetonide nasal spray	15% (v/v)	Ceftriaxone	500mg/mL
Mometasone furoate nasal spray	15% (v/v)	Histamine hydrochloride	2mg/mL
Fluticasone propionate nasal spray	15% (v/v)	Alpha interferon	30000U
Budesonide nasal spray	15% (v/v)	Azithromycin	5mg/mL
Oxymetazoline hydrochloride spray	15% (v/v)	Oseltamivir phosphate	10mg/mL
Phenylephrine Hydrochloride	10mg/mL	Meropenem	5mg/mL
Arbidol	32μg/mL	Tobramycin	2mg/mL
Zanamivir	15mg/mL	Hexadecadro	0.2mg/mL
Ribavirin	5mg/mL	Flunisolide	2mg/mL

3.Will this test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.
4.I have a nosebleed after swabbing my nose. What should I do ?
In the unlikely event your nose starts bleeding, apply pressure to your nose until the bleeding stops and consult a healthcare professional. Do not insert the Swab again.
5.Can the test detect various variants of COVID-19 ?
Yes, the following SARS-CoV-2 variants can be detected with the COVID-19 (SARS-CoV-2) Antigen Test Kit: Alpha, Beta, Gamma, Delta and Omicron.
6.What to do if you test positive?
Anyone diagnosed with COVID-19 can pass the virus onto others.
While isolation is no longer a legal requirement, if you test positive for COVID-19, staying at home protects the people in your community.
If you test positive, you should not visit high-risk settings like hospitals and aged and disability care settings:
- for at least 7 days or until symptoms have gone
- unless seeking immediate medical care.

To help protect those around you, we recommend:
- avoiding contact with people who are at higher risk of severe disease
- wearing a mask outside the home
- working from home where possible
- avoiding going to school, public areas, or travel on public transport, in taxis or ride-share services
- practicing good hygiene
- following your local health department's advice when leaving home.

If you have any appointments you cannot miss (visit to a doctor, family violence service or police), let them know in advance that you have COVID-19.
If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the healthdirect helpline on 1800 022 222.

If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report, emailing iris@health.gov.au or calling 1800 809 361 (08:30am to 5:00pm Monday to Friday).

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COVID-19 (SARS-CoV-2) Antigen Test Kit

Note: Use test only one time.

Scan the QR code or visit our website for instructional video, product information and IFU: https://www.biotop6.com/diaghome-covid-19sars-cov-2-antigen-test-kit/

Customer Support Line

02 7908 9566

Customer Service hours

9 AM ~ 8 PM, 7 Days. ~ UTC+10

Components \ REF	ICO-502-B010	ICO-502-B050	ICO-502-B100
	1Test/kit	5 Tests/kit	10 Tests/kit
1. Test Cassette	1x	5x	10x
2. Extraction Buffer Tube	1x	5x	10x
3. Disposable Swab	1x	5x	10x
4. Instructions for Use	1x	1x	2x

Materials required but not provided : Timer

For the sterilized swab

CE 0197 MDR 2017/745 EU Hangzhou Yiguoren Biotechnology Co., Ltd.
CE 0197 MDR 2017/745 EU Jiangsu Rongye Technology Co., Ltd.
CE 0197 MDR 2017/745 EU Jiangsu HXRT MD Co., Ltd.

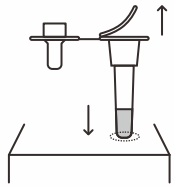
SYMBOLS			
2	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device		Keep away from sunlight
2°C–30°C	Store between 2-30°C		Keep dry
	Consult instructions for use		Do not use if package is damaged and consult instructions for use
LOT	Batch code		Manufacturer
Σ	Contains sufficient for <n> tests	REF	Catalogue number

1



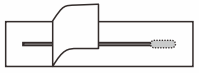
Wash your hands.

2



Tear the aluminum foil on the extraction buffer tube. Place extraction tube into box tube stand.

3



Open the swab package and take out the swab.
Note : Do not touch the swab tip with finger.

4



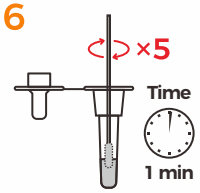
Tilt your head back slightly. Insert the swab about 1.5 to 2.5 cm into one nostril. Gently rotate the swab at least five times against the nasal wall.

5



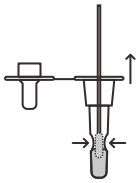
Insert the same swab about 1.5 to 2.5 cm into the second nostril. Again, gently rotate the swab at least five times against the nasal wall.

6



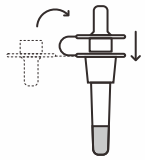
Place the swab in the extraction tube and rotate the swab against the walls of the tube 5 times. Allow the swab to stand in the extraction buffer tube for 1 minute.

7



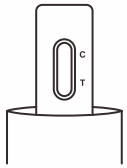
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

8



Press the nozzle cap tightly onto the tube.

9



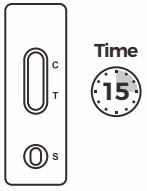
Open the foil pouch and take out the test device.

10



3 drops must be added to the specimen well.

11



Read the result at 15 minutes. Do not interpret the result after 20 minutes.

12



Carefully wrap the used test kit components and Swab samples and dispose in normal household waste.



Note 1: A weak C line could be observed in some cases where strong SARS-CoV-2 positiveresults are obtained.
Note 2: Any faint/weak positive test line counts as a positive result, please follow the corresponding guidance above.

Interpretation of results

POSITIVE: Two colored lines appear on the membrane. One line appears in the control region (C) and the other line appears in the test region (T).
NEGATIVE: Only one colored line appears in the control region (C). No colored line appears in the test region (T).
INVALID: Control line fails to appear.

Caution

For positive results: If you have a COVID-19 POSITIVE result, follow current Department of Health advice (Refer to FAQ #6).
For negative results: If you have symptoms like fever, cough and/or shortness of breath. Please retest in 1-3 days. You must continue following the applicable hygiene and distancing rules even with a negative result. If symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care.
For invalid results: Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.
If an invalid result is produced, the user should review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test Cassette immediately and contact your local distributor.