Hough
COVID-19
Home test

Instructions for Use

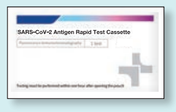
For use with nasal swab specimens
For in vitro diagnostic use only
For home use
Store at 2°C -30°C

QR CODE INSERT

Please scan the QR code to download the Hough App that includes step by step instuctions and videos for additional support.

You can also visit our website at www.houghcovid.com or call our 24/7 Hotline on 1800 0 468 44 for more support.

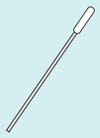
TEST PROCEDURES

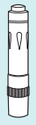


Test Cassette


Extraction Tube & Cap


Extraction Buffer


Swab

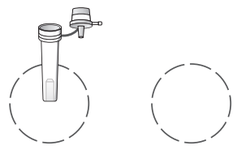

UV flashlight

Instructions for Use

Before starting to test, wash or sanitise your hands and make sure they are dry. The Test must be used within seven days of onset of symptoms.

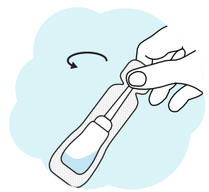
Step 1

Empty box and pop out the extraction tube holder.



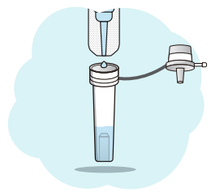
Step 2

Break the tip of the single use vial with the extraction buffer.



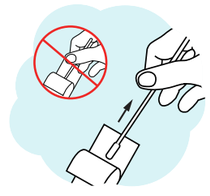
Step 3

Pour all the extraction buffer inside into the extraction tube.



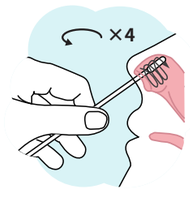
Step 4

Remove the swab from pouch. Do not touch swab tip.



Step 5

Gently insert the swab up to 1-2 centimetres into the nostril. Roll the swab around the inside wall of both nostril at least 4 times. Note: False negatives may occur if the nasal swab is not properly collected.

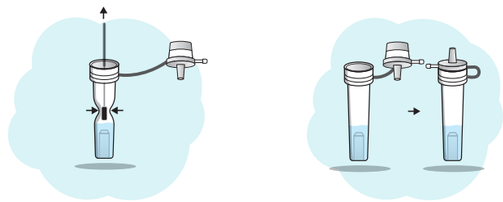


Step 6

Insert the swab into the extraction tube and swirl the swab about 5 times while submerged to mix the sample vigorously in the buffer.

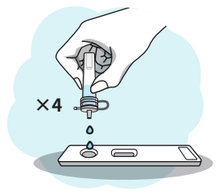
Step 7

Squeeze out as much liquid as possible from the swab by pinching the side of the flexible extraction tube. Press the cap tightly onto the extraction tube.



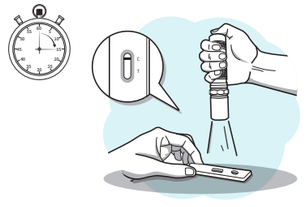
Step 8

Remove test cassette from foil pouch and place the test cassette on a flat surface. Apply 4 drops of extracted sample to the sample well of the test cassette. Dispense the sample at 90 degree to allow for free falling drops and avoid bubbles.



Step 9

After 15 minutes of development time, illuminate the result window with a UV flashlight to observe the test result.



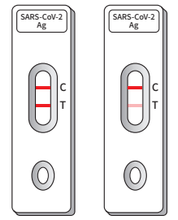
Step 10

Dispose of used swab and cassette in the trash. Ensure you wash your hand thoroughly.

NOTE: Long time exposure to UV light will lead to fading of sample fluorescence intensity and may affect the interpretation of result. Do not expose the cassette to UV flashlight before the specified 15-minute test development.

INTERPRETATION OF RESULTS

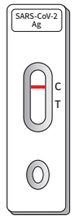
Positive



Positive: If a visible red fluorescent band appears in the test region (T) and the control region (C) at the same time, the test is SARS-CoV-2 N protein positive. (A faint line is still an Indication of a SARS-CoV-2 N Protein Positive.)

IF YOUR RESULT IS POSITIVE, YOU MUST IMMEDIATELY ISOLATE, CONTACT THE AUTHORITIES IN YOUR STATE OR TERRITORY AND ARRANGE TO HAVE A LABORATORY PCR TEST.

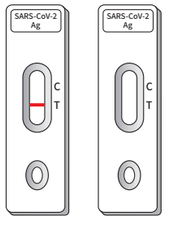
Negative



Negative: If a red fluorescent band becomes visible in the control region (C), and no visible red fluorescent band in the test region (T), the test is SARS-CoV-2 N protein negative.

NEGATIVE RESULTS MAY NOT MEAN THAT A PERSON IS NOT INFECTIOUS AND IF SYMTOMS ARE PRESENT YOU SHOULD ARRANGE TO HAVE A LABORATORY PCR TEST.

Invalid



Invalid: If there is no visible red fluorescent band in the control region(C), regardless of whether there is a red fluorescent band visible to in the detection area(T), the test result is invalid and the sample needs to be tested again with a new test cassette.

INTENDED USE

The Hough Covid-19 Home Test is a lateral flow fluorescence immunochromatography assay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens from individuals with symptoms or other epidemiological reasons to suspect a SARS-Cov-2 infection. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 13 years or older or adult collected anterior nasal swab samples from individuals aged 7 years or older. The Hough Covid-19 Home Test is intended for use in patients within 7 days of symptom onset.

The Hough Covid-19 Home Test is authorized for non-prescription home use.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease caused by SARS-CoV-2. 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 diarrhoea may also be found in some cases.

PRINCIPLES OF THE PROCEDURE

The genome of coronavirus encodes spike protein, envelope protein, membrane protein and nucleocapsid. In the process of viral assembly, N protein binds to viral RNA and leads to the formation of spiral nucleocapsid. N protein is a highly immunogenic phosphoprotein, which is related to viral genome replication and cell signalling. Because of the conserved sequence of N protein, detection of SARS-CoV-2 N protein is of great clinical significance.

The SARS-CoV-2 N-antigen in the sample forms a complex with the antibody labelled with fluorescent particles and the other antibody on the sample pad 2. This complex migrates along the membrane and is captured by the test region (T-line). Unbound fluorescent particles migrate along the membrane to the control region (C-line) and are bound by the control region antibody. The test result in the test window is made visible with a UV flashlight with a wavelength of 365 nm. If both the T-line and the C-line fluoresce, the test result is SARS-CoV-2 N-antigen positive; if only the C-line fluoresces and no T-line become visible, the test result is SARS-CoV-2 N-antigen negative. If no C-line becomes visible the test result is invalid and the sample must be retested with a new test cassette.

KIT COMPONENTS

Note: This kit comes in packs of 2 or 5 tests. The number of items in the kit supplied will depend on which pack is purchased.

- Instructions for Use
- Quick Reference Guide
- Swab
- Test Cassette in a foil pouch
- Extraction Buffer Vial
- Extraction Tube with Cap
- UV Flashlight

Materials Required but Not Provided

Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only. Do not use after expiration date.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Samples should be considered as potentially infectious.
- Do not mix components from different kits.
- Wash hands thoroughly or use hand sanitizer after handling.
- This test should be performed at 15-30°C. The test and samples must be brought to room temperature before the test is performed.
- Follow the Instructions for Use carefully. The accuracy of the assay results cannot be guaranteed if there is any deviation from the Instructions for Use.
- Wipe and wash away any sample spills with highly effective disinfectant. Avoid splashing and the formation of aerosols.
- Use a new clean disposable buffer vial/extraction tube for each sample to avoid cross contamination.
- Do not look directly into the UV light.
- Once the test cassette is removed from the pouch, perform the test as soon as possible to avoid being humidified. The test cassette is sensitive to humidity as well as to heat.
- Do not use the test cassette if the pouch is damaged or if the seal is broken.
- The test cassette cannot be reused.
- The provided Buffer Bottle contains <0.1% sodium azide as a preservative which may be toxic if ingested. If you get buffer solution into your eyes rinse for at least 15 minutes under running water. If irritation persists, go to a doctor.

STORAGE CONDITIONS AND SHELF LIFE

The test can be stored at 2°C-30°C for 12 months from the date of manufacture. Do not store in direct sunlight. Do not use the kit after the date of expiration indicated on the package.

SAMPLE REQUIREMENTS

Applicable to anterior nasal swab samples. It is recommended that the samples are tested immediately at the time of sample collection.

LIMITATIONS

- The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage or repeated freezing and thawing of the sample may affect the test result.
- If the test is not performed within 7 days of symptom onset, false negatives may occur.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- This is a presumptive test only and requires confirmation of positive results by a PCR laboratory and follow up clinical care.
- A positive result does not guarantee infection.
- Repeat testing within 1 - 3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.
- Negative results may not mean that a person is not infectious, and if symptoms are present, the person must seek immediate further testing by PCR.
- False negative results may occur if swabs are stored in their paper sheath after specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Reading the results earlier than 15 minutes or later than 20 minutes may give incorrect results.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Swab sample after heat inactivation may affect the accuracy of the detection and may lead to erroneous results.

PERFORMANCE CHARACTERISTICS

Limit of Detection

The Limit of Detection (LoD) of the SARS-CoV-2 Antigen Rapid Test Kit is confirmed as 1000 $TCID_{50}$/mL.

Cross-reactivity and Microbial Interference Studies

The following cross-reactants and microorganisms had no impact on the performance of the Hough Covid-19 Home Test:

Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus, Adenovirus, Human Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A , Influenza B, Enterovirus, Respiratory syncytial virus, Rhinovirus, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Staphylococcus aureus, Staphylococcus epidermidis, Mycobacterium tuberculosis, Pneumocystis jirovecii.

Hough Covid-19 Home Test might have cross-reactivity with human coronavirus HKU1 and SARS-CoV because they have high homology to the SARS-CoV-2.

Endogenous Interference Study

The following potentially interfering substances had no impact on the performance of the Hough Covid-19 Home Test:

Bilirubin, Triglyceride, Hemoglobin, a-interferon, Zanamivir, Ribavirin, Oseltamivir, Levofloxacin, Ceftriaxone, Meropenem, Tobramycin, HAMA, Whole Blood, Menthol, Naso GEL (NeilMed), CVS Nasal Drops (Phenylephrine), Afrin (Oxymetazoline), CVS Nasal Spray (Cromolyn), Zicam, Sore Throat Phenol Spray, Tobramycin, Fluticasone Propionate.

Clinical Evaluation

The sensitivity of the test was determined with 34 PCR confirmed positive swab samples. The specificity was determined with 141 PCR confirmed negative swab samples. A sensitivity of 94.12% (32/34 known confirmed Postives) and a specificity of 100.00% (141/141 known confirmed Negatives) were determined for the SARS-CoV-2 Antigen Rapid Test Kit.

Detection Against Viral Variants

This test is not affected by variants Alpha, Beta, Gamma, Delta, Kappa, Epsilon, and Lambda.

PROCEDURAL NOTES

Read the Instructions for Use carefully before performing the test.

Testing needs to be performed under proper testing conditions.

Protect the test cassette from moisture.

All reagents and samples should reach room temperature before use.

Do not use turbid or contaminated samples.

EXPLANATION OF THE SYMBOLS USED

IVD	In vitro diagnostic medical device		Consult Instructions for Use
REF	Catalogue Number	2°C 30°C	Temperature Limit at 2°C~30°C
LOT	Batch Code	Σ 2	Contents Sufficient for 2 Cassettes
	Manufacturer	Σ 5	Contents Sufficient for 5 Cassettes
	Date of Manufacture		Do Not Re-use
	Use by date		Caution
	Do Not Use if Package is Damaged		Keep Dry

GENERAL INFORMATION

Manufacturer

Name: Biohit Healthcare (Hefei) Co., Ltd.

Address: Biouhan Bio-Industrial Park, Northeast Corner, Intersection of Kongquetai Road and Chang'an Road, High-tech Zone, 230000 Hefei, Anhui Province, PEOPLE'S REPUBLIC OF CHINA

Tel.: +86 551 65652770

Email: market@chinabiohit.com

Authorized representative in Australia

Name: Hough Pharma PTY LTD

Address: 387 Benowa Road Benowa 4217

Tel: 1800 0HOUGH or 1800 046 844 (24/7)

Email: Enquiries@houghpharma.com

DATE OF ISSUE

Hough Covid-19 Home Test insert

Version 04, October 12, 2021

IMPORTANT CONTACTS

- **TGA Medical Device Incident Report**

Phone : 1800 809 361

Email: iris@tga.gov.au

Testing locations can be found by calling the numbers below or visiting these websites.

- **Australian Capital Territory Department of Health**

General Enquiries: 02 5124 9213

Coronavirus helpline (8am to 8pm daily) :02 6207 7244

Website: https://health.act.gov.au/

- **New South Wales Department of Health**

General enquiries: 1300 066 055

Coronavirus hotline (Service NSW, 24/7): 137 788

Website: https://www.health.nsw.gov.au/

- **Northern Territory Department of Health**

General enquiries: 08 8922 8044

Coronavirus hotline (National helpline): 1800 020 080

Website: https://health.nt.gov.au/

- **Queensland Department of Health**

General enquiries: 13HEALTH or 13 432 584

Coronavirus hotline: 134COVID or 134 268

Website: https://www.health.qld.gov.au/

- **South Australian Department of Health**

General enquiries: 1300 232 272

Coronavirus hotline (9am to 5pm daily): 1800 253 787

Website: https://www.sahealth.sa.gov.au/

- **Tasmanian Department of Health**

General enquiries: 1300 135 513

Public Health Hotline (coronavirus): 1800 671 738

Website: https://www.health.tas.gov.au/

- **Victorian Department of Health**

Department of Health and Human Services: 1300 650 172

Victorian coronavirus hotline (24/7) : 1800 675 398

Website: https://www.dhhs.vic.gov.au/

- **Western Australian Department of Health**

General enquiries 08 9222 4222

Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri)

Website : https://www.healthywa.wa.gov.au/