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

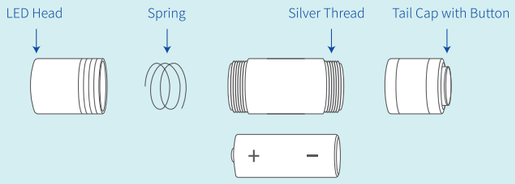
Please scan the QR code to download the Hough App that includes step by step instuctions and videos for additional support.

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

TEST COMPONENTS

Test Cassette, Extraction Tube & Cap, Extraction Buffer, Swab, UV Flashlight, Instructions for Use

TORCH ASSEMBLY



User Instructions

1. Remove the plastic from the battery.
2. Unscrew and remove the tail cap of the torch.
3. Insert battery with positive side first, i.e. the positive end facing the LED head.
4. Replace the tail cap.
5. Press the button at the end of the torch to operate.

Note

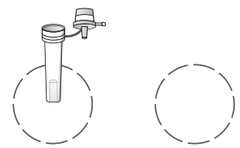
DO insert the batteries properly.
DO preserve battery life by removing the batteries when it is not expected to be used for extended periods of time.
Do NOT shine UV light directly into eyes.
Do NOT use UV light irresponsibly. Adult supervision only.

TEST PROCEDURES

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.

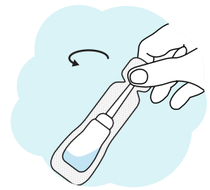
Step 1

Empty box and pop out the extraction tube holder.



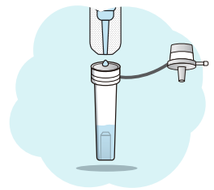
Step 2

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



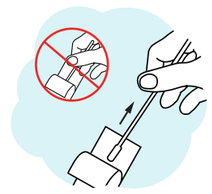
Step 3

Pour all the extraction buffer inside into the extraction tube.



Step 4

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



Step 5

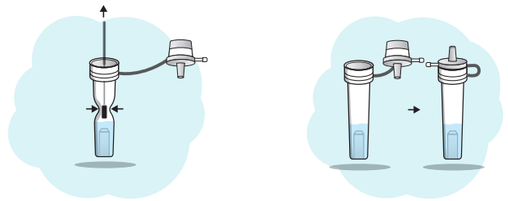
Gently insert the swab up to 1-2 centimetres into the nostril. Roll the swab around the inside wall of both nostril at least 4 times. Note: False negatives may occur if the nasal swab is not properly collected.

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.

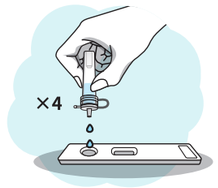
Step 7

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.



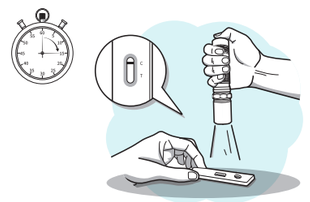
Step 8

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.



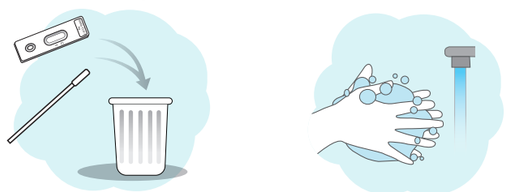
Step 9

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



Step 10

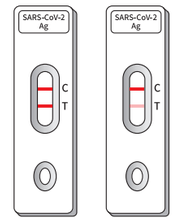
Dispose of used swab and cassette in the trash. Ensure you wash your hand thoroughly.



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

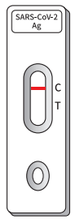
Positive



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 RESULT IS POSITIVE, PLEASE FOLLOW GUIDANCE FROM YOUR LOCAL STATE OR TERRITORY HEALTH DEPARTMENT ON CONFIRMATION TESTING. IF NECESSARY AND IF UNWELL, PLEASE SEEK MEDICAL ASSISTANCE.

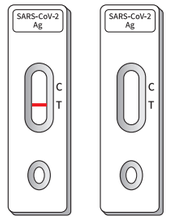
Negative



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 UNWELL, PLEASE SEEK MEDICAL ASSISTANCE.

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, 5 or 25 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
- AA Battery

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.
- Don't attempt to recharge the battery, take the battery apart, or dispose of in a fire as this may lead to leakage or rupture.

STORAGE CONDITIONS AND SHELF LIFE

The test can be stored at 2°C-30°C. 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. Specimens should be tested immediately after collection for best performance. Inadequate specimen collection or improper handling, storage, and transport may yield inaccurate test results.

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. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- 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. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- 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.
- Users with lens replacements in eyes might not be able to see clearly the line.

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

The test can detect variants Alpha, Beta, Gamma, Delta, Kappa, Epsilon, Lambda, and Omicron.

CHEMICAL AND SAFETY INFORMATION

The extraction buffer in the vials contain the following hazardous ingredient. Wash with running water immediately if the extraction buffer solution contacts the skin or eye.

- Reagent: ProClin™ 300
- Hazard: Harmful if swallowed or inhaled. May cause skin burns and eye damage. May cause an allergic skin reaction.

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 n	Contents Sufficient for <n> Cassettes
	Manufacturer		Do Not Re-use
	Date of Manufacture		Caution
	Use by date		Keep Dry
	Do Not Use if Package is Damaged		

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: 1/39 Tallebudgera Creek Road, Burleigh West QLD 4220, Australia
Tel: 1800 0HOUGH or 1800 046 844 (24/7)
Email: enquiries@houghpharma.com.au

DATE OF ISSUE

Hough Covid-19 Home Test insert
Version 10, December 01, 2022

IMPORTANT CONTACTS

For assistance in performing your Hough Covid-19 Home Test or to report any problems associated with the performance of the test, please contact:

Hough Pharma
Phone: 1800 0 468 44
Email: enquiries@houghpharma.com.au
Online: houghpharma.com.au

To report poor performance or usability issues in the self-test environment, report an issue via:

- TGA Medical Device Incident Report

Phone : 1800 809 361
Email: iris@tga.gov.au

For guidance and information about any requirements you may need to adhere to please contact your local State and Territory Health Department on the numbers below or visit the relevant website.

- 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/