Instructions for Use

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

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 nostrils 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.

Step 11
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: 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: 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 symptoms are present you should arrange to have a laboratory PCR test.

Invalid: If there is no visible red fluorescent band in the control region (C), regardless of whether there is a red fluorescent band visible 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 test 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 anterior nasal (nares) swab samples from individuals aged 13 years or older. This 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 coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease caused by SARS-CoV-2. Currently, patients infected with 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 to lead to the formation of viral 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 test 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 light source with a wavelength of 365 nm. 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 becomes 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 collected 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 stored at 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/extension 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 body label with fluorescent particles and the other antibody on the test window is made visible with a UV light source with a wavelength of 365 nm. 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 becomes 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.

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 suspicious 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 other 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 calculated as 1000 TCID₅₀/mL.

Cross-reactivity and Microbial Interference Studies
The following cross-reacts and microorganisms had no impact on the performance of the Hough Covid-19 Home Test:

Endogenous Interference Study
The following potentially interfering substances had no impact on the performance of the Hough Covid-19 Home Test:
- Aspirin, Naproxen, Ibuprofen, Zyrtec, Claritin, Dristan, Sudafed, Excedrin, Aleve, Advil, Motrin, Vicks Vaporub, Vicks Inhalation Mist, Vicks Nasal Spray.
- Ceftriaxone, Ciprofloxacin, Erythromycin, Gentamicin, Amoxicillin, Cephalosporin, Metronidazole, Macrolide, Fluoroquinolone, Clindamycin, Erythromycin, Ciprofloxacin, Gentamicin, Amoxicillin, Ceftriaxone, Doxycycline, Tetracycline, Macrolide, Fluoroquinolone, Clindamycin.

Detection Against Viral Variants
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 Positive) and a specificity of 100.00% (141/141 known confirmed Negative) were determined for the SARS-CoV-2 Antigen Rapid Test Kit.

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.

EXPLANATION OF THE SYMBOLS USED

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<tr>
<th>Symbol</th>
<th>Description</th>
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<td>In vitro diagnostic medical device</td>
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- Western Australian Department of Health General enquiries: 08 8922 8044
- Coronavirus hotline (Service NSW, 24/7): 137 788
- Western Australian Department of Health Coronavirus hotline (National helpline): 1800 020 060
- Western Australian Department of Health Website: https://www.health.wa.gov.au/